PLAYING CAT AND MOUSE: CONTESTS OVER REGULATORY CATEGORIZATION OF DIETARY SUPPLEMENTS IN THE U.S.

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ABSTRACT

Regulatory categorization can be a matter of life and death to firms as it sets legal limitations to the production and sales of their product. In this paper, we set out to uncover this critical process, for which there is only anecdotal information in extant literature, by asking, how are regulatory categories determined through the strategies and interaction of firms, regulators and other category audiences? We use extensive archival data to examine how US dietary supplement makers first moved from drug to food category in 1976 and when faced resistance from the FDA, created an entirely new category in 1994, which fueled their explosive market growth since then. Our findings show that regulatory categorization is a contest between firms and the regulator, where firms try to disrupt unfavourable regulation by overpowering the regulator through hard power imposed by other state actors, which is achieved through pressure from another category audience, consumers, who are themselves won over through soft power.

Keywords: regulatory categorization, institutional work, corporate political action, soft power, category creation

INTRODUCTION

E-cigarettes have been around since the early 2000's. The product is well understood and clearly demanded by masses, with a US market size of $1.5 billion today. However, as of May 2016, new FDA regulations came into effect to categorize e-cigarettes as "tobacco products" rather than "drug delivery devices", which requires them to obtain pre-market approval and carry "Smoking kills" labels, while their sale to minors and inclusion in checked baggage on flights will be prohibited. These new restrictions are expected to block more than 99% of current e-cigarette products and blow "major smoke on the industry" (Burke, 2015).

As this example illustrates, *regulatory categorization*, which sets legal limitations to the production and sales of products, can be a matter of life and death to firms. Most studies on categorization focus on *product categories*, i.e. categories in which firms position products within a distinct market segment for sale (Lounsbury & Rao, 2004, Vergne & Wry, 2014). However, in regulated markets (e.g. finance, food, healthcare), which constitute a large proportion of the world economy, firms also have to obtain a *regulatory category*, which is a process where the terms and conditions under which a product is made and distributed are specified under the law (Funk & Hirschman, 2014). This process is likely to be independent from product categorization. Like e-cigarettes above or the 2017 ban of Uber in London which caused thousands to protest on the streets, a product may be well understood and demanded by consumers, but still blocked or severely restricted due to their regulatory category. In this paper, we set out to uncover this critical but unexplored process of regulatory categorization, by asking, *how are regulatory categories determined through the strategies and interaction of firms, regulators and other category audiences*?

Given the limited theory and empirical evidence on our research question, we conducted an inductive study (Eisenhardt, 1989). Based on archival data including articles from 375 trade journals, 80 academic journals, and 138 newspapers, 11 books, 6 congressional hearings,

and 47 interviews, we traced longitudinally how US dietary supplement makers first moved from the drug to the food category in 1976, and when the FDA attempted to recategorize them, created an entirely new regulatory category for themselves in 1994.

Our findings unveil that unlike product categorization, regulatory categorization occurs through a *contest* between firms and the regulator, where firms try to disrupt unfavourable regulation by overpowering the regulator through other state actors that can impose hard power (Nye, 2004) through new laws and rulings. We also find, however, that such hard power is assembled through the indirect influence of other category audiences, e.g. consumers, who are themselves won over through soft power. These findings contribute to institutional work by identifying the important role of *soft power* (Nye, 2004; Santos and Eisenhardt, 2009) within *advocacy work* (Lawrence and Suddaby, 2006). We show that influencing a target category audience through activation of other audiences requires activating these audiences in the right sequence and through targeted arguments. This emphasizes the critical role of exercising power *through* other actors (Fleming and Spicer, 2016) in the regulatory space and answers previous calls (e.g. Grodal and Kahl, 2017) to bring a power perspective into categorization. At a broader level, we address the need for "explicit empirical studies of the fundamental relationship between power and institutions" (Lawrence and Buchanan, 2017: 525) and help raise awareness of power in institutional theory (Lawrence, 2008; Munir, 2015; Rojas, 2010).

Our findings also contribute to institutional work during categorization through the introduction of *category work*, through which actors prepare critical audiences cognitively for category change. Our work unpacks category work through the mechanisms of dissociating from current category, associating with target category and selective representation. In addition, we contribute to extant work on category change versus new category creation (e.g. Durand and Khaire, 2017) by showing that in the regulatory space, both category change and

new category creation can be tools to overpower hostile state actors, but that the latter entails dissociation from *both* the extant category and its evaluator through a frame of innovation in the public interest.

Finally, our multi-stakeholder account of regulatory categorization provides insights into the actions of regulators and category incumbents. Our comparison between regulated firms and the regulator reveals how the limitations of regulators in generating advocacy among public can lead to power struggles with other state actors such as Congress and affect the ultimate categorization. Regarding category incumbents, our findings provide a nuance to findings on strong ties between industry incumbents and state actors (e.g. 'revolving doors', Eckert, 1981; Hillman and Hitt, 1999) by showing that in the categorization of new products and services, the split between different category incumbents over whether to diversify into these products and services or resist them can be an important opportunity for market entrants to shape the categorization in their favor. Overall, our findings unveil regulatory categorization as a highly political, multi-actor process where soft power to activate key category audiences can help small firms overpower resistance from powerful state authorities.

THEORETICAL BACKGROUND

Categories are socially constructed partitions or taxonomies that divide the social space into groupings of objects perceived to be similar by external audiences[1] (Bowker & Star, 2000; Negro et al., 2010; Suarez et al., 2015). In the context of markets and organizations, categories provide "a cognitive infrastructure that enables evaluations of organizations and their products, drives expectations, and leads to material and symbolic exchanges" (Durand & Paolella, 2013: 1102). Studies show that category membership affects firm performance and governance (Zuckerman 1999, 2000; Hsu 2006; Rindova et al., 2011), inter-firm rivalry (Porac et al., 1995), and market emergence (Rosa et al., 1999; Garud et al., 2010).

[1] An audience is a group of individuals or organizations with mutual dependence with an organizational category (Vergne and Wry, 2014).

While earlier sociological research (e.g. the category imperative) treated categories as expectations and rules that audiences impose on firms (Hsu & Hannan, 2005; Zuckerman, 1999; see Durand & Paolella, 2013 for a review), more recent work argues that given its impact on their survival, firms are likely to influence the categorization process (Kennedy, 2008; Khaire & Wadhwani, 2010; Navis & Glynn, 2010, Jones et al., 2012; Grodal & Kahl, 2017), e.g. through signaling affiliation with favorable product categories[2] (Vergne, 2012; Zhao et al., 2013) or even originating new categories (Kennedy, 2008; Navis & Glynn, 2010; Khaire & Wadwhani, 2010; Jones et al., 2012; Grodal et al., 2015).

Scholars have also started to explore *how* firms use strategy to influence categorization (Pontikes & Kim, 2017), for instance through deliberate language and labels[3] to create or contest new categories (Granqvist et al., 2013; Kennedy, 2008; Khaire & Wadwhani, 2010). Jones et al. (2012) show how category entrepreneurs use extant institutional logics associated with their specific mix of clients to construct, contest, and elaborate new categories. In these studies, scholars highlight the role of the category audience, which is a transposition of the stakeholder concept from the organization to the organizational category level (Vergne & Wry, 2014). Category audiences may include consumers, investors, employees, certification agencies, government institutions, and analysts (Hsu et al., 2009). Recently, Grodal et al. (2015) theorized that these audiences not only evaluate categorical claims, but also engage in category creation. While these studies recognize agency during categorization, they largely focus on labelling and meaning construction through language to inform and convince audiences (Grodal and Kahl, 2017). We argue that this focus on language and cognitive processes in categorization undermines the role of power battles, which are likely to shape certain categorization processes, e.g. regulatory categorization, as explained below.

[2] Product categories are defined as categories in which firms position their products within a distinct market segment for exchange between producers, buyers, etc. (Lounsbury and Rao, 2004, Vergne and Wry, 2014).

[3] A market label is a type of symbol used to signify membership in a particular market category (Granqvist et al., 2013).

Regulatory Categorization

Product categories are not the only categories firms are subject to. Many industries are regulated, and entry and operations in these require *regulatory categorization*, a process where the terms and conditions under which a product is made and distributed are specified under the law (Funk & Hirschman, 2014). In the United States, for example, 25% of all consumer expenditures totaling $1 trillion occur in FDA regulated industries (Okie, 2010). Other examples include the FCC regulated telecommunications industry of $400 billion revenues, and financial services of $900 billion (US Department of Commerce, 2014), which is overseen by a set of regulators including the Federal Reserve Board and SEC. In these environments, regulatory categorization can severely affect firms' critical decisions regarding production, time to market, marketing and sales, leading to significant costs during these processes and limiting survival, particularly for entrepreneurial firms with limited resources that depend on sales from one product.

While mostly assumed in literature to happen simultaneously with product categorization (Vergne & Wry, 2014), regulatory categorization is a distinct process that deserves attention. As our opening example on e-cigarettes shows, a product may be well understood and categorized into a market segment by consumers, but blocked or severely restricted due to its regulatory category. In addition, regulatory categorization is likely to differ from product categorization through the asymmetrical power structure among different regulatory category audiences due to the critical role of state actors, i.e. regulators, to decide on the appropriate regulatory category or sub-category, its boundaries, and therefore the relevant actors, relationships, and activities (Funk & Hirschman, 2014). In other words, regulatory categorization is a process where firms are dependent on a highly powerful state actor with full authority over their survival and that involves concrete events and decisions.

To our surprise, knowledge on this unique process that is critical for firm survival

comes primarily from anecdotal stories in conceptual pieces. For instance, a theoretical piece by Kennedy & Fiss (2013) documents how, faced with an anti-trust lawsuit, Microsoft attempted to re-categorize its business in a new category of 'information at your fingertips' market, which is recognized today as the search market. A review by Vergne & Wry (2014) gives the example of how Dr. Pepper argued against cola producers that its product was not made from coca leaves to change its category to "non-cola" to allow independent bottlers to carry it. The authors also discuss how the Uber car service entered a political fight with regulators and taxi commissions over its regulatory category (Chen, 2012), arguing that it should not pay licensing fees or be subject to regulatory restrictions for taxis as "a technology company connecting riders to drivers" (Vergne & Wry, 2014). These anecdotal cases emphasize the political nature of regulatory categorization and the prominence of agency in the process. However, in addition to lacking a theoretical lens, these cases do not reveal the specific interactions between firms, regulators, and other audiences, and what led to the eventual categorization. Following a call by Vergne & Wry (2014) to go beyond anecdotes and examine empirically how regulatory categories are determined through political contestation among various actors, we investigated which research streams might shed light on the political nature of regulation and in particular, the contestation between firms, regulators and other critical actors.

The Politics of Regulation

Our investigation revealed that within organizational studies, two distinct research streams, corporate political strategy and institutional work, are concerned with firms' attempts to influence regulation and their interactions with other parties in the process. Below, we discuss each stream with its main findings and shortcomings.

Corporate Political Strategy. This research stream directly deals with firms' interaction with state actors such as legislators (Hall & Deardorff, 2006; Macher, Mayo, & Schiffer,

2011; Choi, Jia, & Lu, 2015) and regulators (Holburn & Vanden Bergh, 2008, Haeder & Yackee, 2015). While recognizing that firms invest vast resources and effort to achieve a more favorable regulatory and legislative environment (Bonardi et al., 2005; Hillman & Hitt, 1999; Schuler, Rehbein, & Cramer, 2002; Shaffer, 1995), scholars typically focus on two specific types of actions. The majority of research is on *direct* political actions, e.g. lobbying (Schuler, 1996; de Figueiredo & Tiller, 2001; de Figueiredo & Kim, 2004; Baumgartner et al., 2009) and political (financial) contributions (Hansen & Mitchell, 2000; Ansolabehere, Snyder and Tripathi, 2002), mainly due to the general availability of this kind of data.

Only a few studies in this stream focus on *indirect* actions such as corporate grassroots and constituency-building efforts to mobilize stakeholders (Baysinger, Keim, & Zeithaml, 1985; Heath, Douglas, & Russell, 1995; Hillman & Hitt, 1999; Lord, 2000, 2000b, 2003; Walker, 2012). Empirical work by Lord (2000) found, for instance, that constituency building was very effective to influence the passage of legislation and that those forms of constituency feedback requiring more effort (e.g., individual letters and phone calls) were more influential than emails or signed petitions. The Shaffer & Ostas' (2001) study of "lemon" laws showed that large automobile manufacturers who opposed lemon laws were not as effective as the smaller automobile dealers who supported the laws with the backing of an energized consumer lobby. Finally, Walker (2012), in a rare attempt to explore both direct and indirect political actions, confirmed that politically active firms use both lobbying and constituency building to influence, but has not examined these processes and their interaction. Overall, corporate political strategy studies begin to uncover how firms can influence regulators, legislators and other state actors. However, influence is mostly shown as one-directional and state actors as targets of influence rather than active parties in the process.

Institutional Work. Many studies on categories (e.g. Khaire & Wadhwani, 2010; Meyer & Hollerer, 2010; Vergne & Wry, 2014; Wang, Wezel, & Forgues, 2016) already refer to

institutional theory as a complementary theoretical frame as “norms and regulations can make many categorizations illegitimate or illegal, and changes in regulation may have a catalytic, perpetuating, or detrimental impact on categories”, making it imperative for actor engaged in categorization to act aligned with the habitual and legitimate behavior in a given institutional setting (Durand et al, 2017: 13). Looking at regulatory categorization as an interaction between regulators, regulated parties and other audiences makes institutional theory, and particularly the institutional work perspective, which views institutional change as emerging from interactions of various actors acting according to their interests (Lawrence & Suddaby, 2006; Lawrence et al., 2009), an appropriate lens to study this process.

In their seminal book chapter, Lawrence and Suddaby (2006) categorized institutional work based on intended outcomes. In *creating institutions*, they pointed out the role of overtly political work such as 'vesting' and 'defining', in which actors reconstruct rules, rights and boundaries that define access to resources. Advocacy work, on the other hand, aims at mobilizing political and regulatory support for creating institutions (Lawrence and Suddaby, 2006), with the most prominent example being lobbying, e.g. by industry associations or social movements (Clemens, 1993; Holm, 1995; David et al., 2012; Galvin, 2002; Granovetter & McGuire, 1998; Greenwood et al., 2002; O’Mahony & Bechky, 2008; Sine et al., 2007; Ingram & Rao, 2004; Lounsbury et al., 2003; Rao, 2009). In addition, 'constructing identities', 'changing norms' and 'constructing networks' focus on actions to reconfigure actors' belief systems while 'mimicry’, 'theorizing' and 'educating' mechanisms involve actions to modify boundaries of meaning systems. In *maintaining institutions,* 'enabling', 'policing' and 'deterrence' predominantly ensure adherence to rule systems, while 'valorizing / demonizing', 'mythologizing' and 'embedding and routinizing' emphasize reproducing existing norms and beliefs. Finally, for *disrupting institutions*, actors disconnect rewards and sanctions from rules

and practices (Leblebici et al. 1991, Holm 1995), and dissociate moral foundations, assumptions and beliefs to legitimize non-compliance (Lawrence and Suddaby, 2006).

Since then, scholars have suggested several other forms of institutional work (e.g. boundary and practice work, Zietsma & Lawrence, 2010; justification work, Jagd, 2011; rhetorical work, Symon et al., 2008; temporal work, Granqvist & Gustafsson, 2016) for changing institutions. However, not many of these touch upon actors' work to change / maintain regulation. An exception is the study by Maguire & Hardy (2009) where the authors showed how disruptors from outside the institutional field used *disruptive work* for abandonment of DDT use in farming practices through regulatory change, whereas inside elites countered this with *defensive work*, arguing that such change was unnecessary. More specifically, the authors found that disruptors authored texts that problematized current practices and framed them as unethical, undesirable, or inappropriate during their call for regulatory change whereas the defenders responded to these assertions again by publishing counter texts. While important as a study tackling regulatory change through institutional work, this study can only inform us partially about the political and complex nature of regulatory categorization due to its heavy focus on the role of language and discourse, similar to studies on product categorization described earlier.

More broadly, when it comes to the regulator/firm relationship, it is noticeable that both in corporate political strategy and institutional work largely consider state actors as indistinguishable and static, focused on reinforcing existing policies for institutional maintenance purposes (Canning and O'Dwyer, 2013; Eckert, 1981; Hilgartner & Bosk, 1988; Kingdon, 1984). It is therefore not clear whether, in the regulatory categorization of a product or service, all state actors will be in agreement or whether any contestation may happen between officially assigned category evaluators (e.g. regulators) and other state actors (e.g. courts, legislators), which would affect the eventual category decision. In their recent

theoretical piece, Rhee et al (2017) argue that when categories need to be determined by a central authority, like in the case of regulatory categories, the process can turn into a game of power, particularly when disagreements arise among various state and private category audiences. Extant literature distinguishes between “hard power” which is based on coercion, direct rewards, and extensive resource deployment to force others' behaviors, from "soft power," which is based on subtle influence mechanisms that cause others to willingly behave in ways that benefit the focal agent (Nye, 2004; Santos and Eisenhardt, 2009). In their recent review of the power construct in institutional studies, Lawrence and Buchanan (2017) identify similar concepts of influence (soft power) and force (hard power) as key constituents of institutional agency, but do not discuss when and how actors may use one or the other, or a combination to achieve institutional objectives.

As Grodal and Kahl (2017) suggest, bringing a power perspective into categorization would help discover the role that conflicting interests among various actors play in shaping category evolution. For regulatory categorization, this would include conflicts among state actors, whose laws and regulations may be subject to influence from various other actors. In this paper, we set out to untangle such processes of power and political contestation by examining firms’ interaction with various category audiences, with a particular attention to the perspectives and actions of regulators and other relevant state actors. Specifically, we explore *how regulatory categories are determined through the strategies and interaction of firms, regulators and other category audiences* in the setting of US dietary supplements.

RESEARCH METHODS

Given the limited theory and empirical evidence on our research question, we conducted an inductive study, which is a good approach to tackle process-based research questions that extant theory does not address well (Eisenhardt, 1989). In order to obtain rich and detailed data on our multi-faceted research question (Yin, 2003), we used a single-case design,

focusing on the US dietary supplement industry. Case studies are detailed empirical descriptions of particular instances of a phenomenon that are based on a variety of data sources (Eisenhardt & Graebner, 2007). In particular, single cases allow immersion in rich data, which can help sharpen existing theory by pointing to gaps and beginning to fill them. They can also provide inspiration for new and untested ideas (Siggelkow, 2007).

Our research setting is the US dietary supplement industry. We examine the regulatory changes in this industry starting from 1940's, but with a particular focus on the regulatory categorization of dietary supplements between 1973 and 1994, when the majority of the categorization related actions took place. This setting is particularly appropriate for our study for several reasons. First, dietary supplements were introduced into an established industry with an active and powerful regulator, the Food and Drug Administration (FDA from here on). This makes regulated firms' influence efforts much more critical in shaping the regulatory categorization process. The presence of an active regulator also allows us to observe the regulator's perspective and actions to create a multi-actor view of regulatory categorization. In addition, although we have a single case, the case consists of two "phases", i.e. two category changes taking place in 1976 and in 1994, which allows us to observe similar frames and actions used by firms and regulator leading to success/failure twice, strengthening our results. It also allows us to pinpoint differences between movement between extant categories and new category creation, as explained in detail in the discussion section.

Data Sources. Our data consists of archival documents and interviews (Table 1). We analyzed 375 articles from major industry journals (e.g. Food Labeling News, Food Chemical News) covering 1977-1994, and 138 newspaper articles obtained from Factiva database with the keyword 'dietary supplements' for 1988-1994, and transcripts from six congressional hearings about dietary supplements obtained from Casewatch. To understand the evolution of

the industry more broadly, we also examined 80 articles from academic law journals (1972-2006, with 'dietary supplements' as search keyword) and 11 books written on the topic.

Using archival data is appropriate for our setting for several reasons. First, the large quantity of documents shows the prevalence of publicly accessible communications in the industry and provides historical insight. Second, since a large proportion of these are specialized news articles, they capture important and objective information about how the different parties' opinions and actions and the industry evolved. In addition, academic law journals were critical to capture the public and academic discussion on the matter while books allowed us to reconstruct the background of the case more accurately. Finally, transcripts from congressional hearings (350 pages on average) helped us understand the perspectives and statements of various actors involved in the process.

In addition to these archival documents, we used interviews conducted by leading industry journals with various actors from the industry that were fundamental in the passage of the DHSEA act. We analyzed transcripts from 10 such interviews and integrated them into our case. To avoid a biased perspective, we also examined 238 FDA oral history (interview) transcripts from various FDA commissioners and regional directors from 1968 to 2013. We identified and further analyzed 35 relevant transcripts to obtain pertinent insights on the perception/actions of the FDA. Finally, we did a final validity check by conducting retrospective interviews with two prominent actors who played a fundamental role in the passage of the DSHEA act. We uploaded the data into the NVivo software for further analysis.

----------INSERT TABLE 1 ABOUT HERE----------

Data Analysis. For data analysis, we followed an iterative process of moving back and forth between theory and data, as described below.

Stage 1: We began writing a case history after compiling facts and quotes from newspapers, industry journals and congressional hearings. These sources helped us identify

key stakeholders (e.g. FDA, legislators, trade associations), their perspectives, and strategies. Next, we filled in the gaps from various academic articles and books on supplements. Finally, we integrated the interview transcripts to enrich the data with personal stories and quotes. Each researcher revised the data separately in order to write the case history. The resulting case was 50 pages long. While developing the case history, we also marked key events (e.g. launch of public campaigns, moratoria and new legislation) that shaped the categorization process. In this process, we identified two main phases in our case history, change between extant categories and new category creation, which demarcated our approach to theory building. We put these key events into a timetable (Table 2).

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Stage 2: Once the case history was finished, we revised theory and empirical evidence from prior studies (e.g Granqvist et al., 2013; Vergne and Wry, 2014; Vaccaro & Palazzo, 2015) to compare different phases of our case to corporate political strategy, institutional work and categorization processes described in literature. In the first phase, we discovered first-order concepts (Gioia et al., 2013) such as cultural meta-narratives where supplement manufacturers repeatedly used the argument that FDA was trying to 'take away the American citizen's health care freedom of choice'. We also observed other first order concepts related to the category itself, such as 'redefining relevant attributes for categorizing' or 'food as a label'. For the second phase, we observed other first order concepts such as 'regulator bias and incompetence arguments'. Our analysis suggested that these first order concepts were related to cognitively preparing audiences and generating advocates for category change, which prompted us to delve more into the data.

Stage 3: Next, we reexamined these codes to theorize from the first-order concepts. We discovered that the use of these concepts was central in cognitively preparing audiences for category change and mobilizing them. For instance, interactions with category audiences at

individual and field levels helped move them from disengagement to caring about supplements. We labeled this mechanism 'hooking consumers' (i.e., using values to hook the stakeholders, Vaccaro & Palazzo, 2015). We then proceeded to identify other mechanisms in supplement firms' interaction with critical audiences. We created Tables 3a, 3b and Figure 1 to illustrate how each first order concept relates to the second order themes (mechanisms) we identified. From these, we arrived at two aggregate dimensions; *advocacy work* and *category work.* We did a similar process for FDA's actions (Table 4), identifying first order concepts such as 'redefining relevant attributes for categorization' or 'educational campaign', second order themes such as 'association with target category' and 'educating', and the aggregate dimensions of category work and maintenance work.

----------INSERT TABLES 3a, 3b, 4, FIGURE 1 ABOUT HERE----------

Stage 4: To understand the socio-political process that led to the successful re-categorization of dietary supplements, we also analyzed the actions of other key actors (e.g. Congress, health stores, pharmaceuticals) to create a multi-faceted account. We sharpened our theory through iteration between theory and data, comparing findings to literature to identify similarities and differences to raise generalizability (Eisenhardt, 1989). The emergent theory on the battle between firms and regulators to change/maintain regulatory categories (Figure 2) and within this process, firms' strategic categorization to change between extant categories versus create a new one (Figure 3) are explained below.

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FINDINGS

Before delving into the theoretical framework that emerged from our data, it is useful to give a brief chronological summary of the events that took place within the regulatory categorization of dietary supplements (please see Table 2 and Figure 4 for an overview).

Chronological Summary

When vitamin supplements first emerged in early 40's, the FDA regulated them as foods or drugs on a case-by-case basis. To be considered a food, a supplement had to have taste, aroma, or nutritive value. It was a drug if the label made therapeutic or functional claims such as "calcium builds strong bones", or offered evidence that its intended use was as a drug. As more products, e.g. protein powders, emerged with functional claims (e.g. building muscles), the FDA started to regulate supplements more strictly. In a landmark case in 1948, the FDA sued Kordel Nutritionals for the medicinal claims the firm made in written communications with health stores about its products. The Supreme Court held that the material was part of an integrated marketing plan and could be relied upon in determining the regulatory category of a product. After Kordel, the FDA gained freedom to treat dietary supplements[4] as drugs by broadening the definition to all products with functional or therapeutic claims in their label, leaflet or communication with the retailer. The FDA used this to stop various products from market entry and used courts to get support[5].

In the 1960's and early 70's, vitamins became increasingly popular when experts such as health food advocate Adelle Davis or Nobel Prize winning chemist Linus Pauling promoted them in TV and press. Concerned with this trend, the FDA took action, first by proposing to Congress to require the following disclaimer on dietary supplements in 1968:

"Vitamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements."

Later in 1972, it proposed to require prescriptions for high-dosages of vitamins A and D.

To prevent these policies, supplement makers first sued the FDA in court and obtained a moratorium on FDA's regulations, and then lobbied and convinced Senator Proxmire to pass legislation to move supplements to the food category with the Proxmire Amendment of 1976.

[4] According to our archival data, dietary supplements is the official label for these products, although they were also called food supplements, nutritional supplements, and most frequently simply vitamins throughout the story.

[5] Two prominent examples are the case of Vitamin Industries in 1955 and CDC capsules in 1962.

After Proxmire, the FDA made one more attempt, the Over-the-Counter (OTC) Monograph of 1979, to categorize supplements as drugs. However, this again caused a strong wave of protest, upon which the FDA withdrew its monograph. Subsequently, the FDA assumed a more reactive role, only responding to safety problems or explicit drug claims. While supplements enjoyed high sales growth in the 80's, two public health crises brought FDA's role as a regulator into question. First, in late 1983, E-ferol, a vitamin E solution for infants, caused 38 deaths. Then, in 1988-1989, 37 deaths and 1500 adverse effects occurred due to L-tryptophan being used as an antidepressant or for body-building. During these events, the media blamed the FDA, with the New York Times publicly accusing the FDA: "*If the F.D.A. isn't protecting the public, how can the public protect itself*?" President Bush appointed David Kessler, as Head of the FDA in 1990. With its legitimacy in question[6], the FDA started recollecting L-tryptophan from the market, created a special branch called the "Health Fraud Unit", and sharply increased product seizures (Table 5). To regulate supplements more strictly, the FDA first circumvented the Proxmire Amendment, arguing that dietary supplements in gelatin capsules were "food additive" (thus subject to pre-market approval) as gelatin was food and dietary supplements were added to it. To prove their intent, FDA followed up with a landmark seizure at Traco Labs in 1988, where they confiscated blackcurrant supplements in gelatin capsules. Second, using the Nutrition Labeling and Education Act (NLEA) of 1990, the FDA blocked market entry to many supplements as food products could not make health claims. The FDA also set a new reference daily intake standard to be printed on labels, which resulted in a reduction in daily allowances for 14 most popular vitamins and minerals.

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FDA's efforts to regulate supplements more strictly within the food category again caused great resistance among supplement makers, who formed the Nutritional Health Alliance

[6] Senator Ted Kennedy declared: "The FDA is caught in a downward spiral of declining resources, credibility and morale" (Hurley, 2006).

in 1992 and mounted a national campaign to categorize dietary supplements in a new category "aimed at getting the FDA off the industry's back" (Hurley, 2006), where FDA is not the sole regulator. With the help of Utah Senator Orrin Hatch, they first succeeded to get Congress to issue a moratorium on FDA's reinterpretation of NLEA in 1993. During the time gained by the moratorium, they dramatically increased the intensity of their campaign, which eventually resulted in the Senate passing the 1994 DSHEA bill, mandating the FDA to not require premarket approval of supplements, explicitly excluding supplements from the definition of a food additive, and taking away FDA's sole authority by appointing an NIH Office of Dietary Supplements and a Commission on Dietary Supplement Labels as regulatory authorities. As expected, this enormous victory for supplement manufacturers, which FDA Commissioner David Kessler called his ''greatest failure as the head of the FDA", severely disabled FDA's regulations. In the four years after, annual sales of dietary supplements jumped from 4 to 12 billion Dollars (see Table 6 for sales growth data and Table 7 for regulation after 1994).

As this chronology shows, dietary supplements changed first from the drug category to food, and then from food to the newly created dietary supplement category. Below, we describe how firms' activities and interaction with other actors led to these category changes.

----------INSERT TABLES 6 AND 7 ABOUT HERE----------

Phase 1: Movement between Extant Categories

Supplement Makers' Efforts to Move into the Food Category

As described above, supplement makers first moved to the more favorable food category through the Proxmire Amendment of 1976. This meant that supplement makers disrupted regulation by overpowering the regulator using Congress, which was done through *category work* to prepare critical audiences, Congress and those with power over Congress, cognitively for category change and *advocacy work* to activate them, as described below.

Category Work: Disassociating from current category, associating with target category

Supplement makers used category work to prepare relevant audiences, both public and state actors, cognitively for category change. In particular, they *disassociated* from existing categories and *associated* with the new category through labels and product attributes to change their categorical affiliation. To exit the drug category, supplement makers dissociated supplements from drugs and associated them with food by redefining the relevant attributes for categorization, emphasizing product components, e.g. nutrients that were natural to the body like food and unlike drugs. The National Health Federation bulletin in June 1973 read:

"The FDA is so disease oriented and so drug oriented they seem incapable of understanding the nature of nutritional substances. Nutrients are not, and never will be, drugs per se, regardless of their level of intake or the intent of their use because they are essential and normal in the body's normal environment."

In contrast, FDA's category work, explained in the next section, focused on association through redefinition of relevant attributes for categorizing emphasizing function, i.e. that the intended use of supplements was therapeutic.

To complement this strategy, supplement makers also engaged in labeling strategies to *associate* themselves with the food category. For this, they increasingly used the "food" label to refer to themselves. For instance, Milton Bass, legislative counsel of National Nutritional Foods Association publicly stated in 1974:

"The FDA has very important problems involving the regulation of potent drugs and the high cost of medicines to the American consumer. We submit that it is quite unnecessary for the agency to expend its time and effort in an attempt to restrict the consumer in his freedom to purchase safe food products."

Similarly, John Matonis, representing the Health Industries Institute, declared in a hearing:

"The Proxmire bill would deny FDA the power to prospectively "seize" certain nutritional food products by preventing them from ever being marketed, just because FDA disagrees with a significant block of consumers and nutritionists."

Overall, the move to the more favorable food category entailed category work to cognitively dissociate supplements from the drug category and associate them with the desired one through labeling and redefinition of relevant attributes for categorizing. Table 3b summarizes

the evidence for these mechanisms. While this constituted the cognitive aspect of supplement makers' work to obtain category change, their advocacy work to win over the critical category audiences played a key role in their ability to overpower the FDA, as explained below.

Advocacy Work: Lobbying state actors, hooking-activating-coordinating consumers

Data show that supplement makers, along with the interest groups and industry associations that they pleaded and received great support from (Table 8), used soft power[7] to activate the Congress, first by convincing Senator Proxmire of Wisconsin, a consumer advocate and the author of popular nutritional self-help books. Following organized meetings where Proxmire listened to narratives told by "worried consumers and health stores" in Wisconsin in 1972, supplement interest group National Health Federation visited the senator and told him that fending off FDA regulations in Congress was "the only way for the industry to survive". Proxmire quickly got on board and started to lobby in Congress in favor of supplement makers. While using soft power to activate Congress members against the FDA, supplement makers also gained time through a moratorium. In 1974, three supplement interest groups challenged FDA's proposed rulemaking, which resulted in the US appeals court blocking the FDA with a 6-month moratorium on the enforcement of the new rules.

----------INSERT TABLE 8 ABOUT HERE----------

In addition to getting an advocate inside Congress, supplement makers also lobbied Congress-wide, using economic arguments – e.g. how FDA's restrictions would "sharply increase the cost of vitamins to the public" and "drive the small vitamin and food supplement stores out of business" - to convince 44 other Senators to support their cause.

Simultaneously with engaging the Congress directly, supplement makers also followed a three-step approach to activate another category audience with power over Congress:

[7] Soft power involves subtle influence mechanisms that cause others to willingly behave in ways that benefit the focal agent. In contrast, hard power is defined as coercion, direct rewards, and extensive resource deployment to force others' behaviors (Nye, 2004).

consumers. By hooking, activating, and coordinating consumers, they exercised soft power on Congress. Table 3b summarizes the evidence for these mechanisms.

Hooking consumers through meta-narratives. To 'hook' consumers, i.e. gain their attention (Vaccaro and Palazzo, 2015), supplement makers linked their cause to a meta-narrative[8] based on the cultural identity of the American public. To achieve this, they first framed their cause as a matter of *freedom of choice*[9] and FDA practices as against it. For instance, a National Health Federation spokesman stated:

"Even our oldest and wisest members know that if they have freedom they will still make mistakes and will suffer for them, but so long as some human must make choices about their health, they prefer to play the role themselves."

In a demonstration afterwards, the NHF again used freedom of choice arguments stating that they were protecting "people's freedom of choice in matters of health". As part of this, supplement makers also used lack of evidence for the harm of dietary supplements to convince consumers that taking them should be a choice. In 1974, right after the moratorium, the President of the National Nutritional Foods Association, explained:

"The American concept is that consumers must not only be free to choose, but free to have that choice uninfluenced by government interference…. This is particularly true where the government's evidence in support of its value judgment is sharply contested by a number of experts of impeccable reputation…. As long as he is not dealing with dangerous or untruthfully labeled food, then risk taking [sic] should be for each man to decide for himself…. What purpose is there in discouraging [a hypothetical arthritis] sufferer from pursuing his quest for better health? He is a free man. He is not stupid. … It seems to me that this will be a better country if people are encouraged, rather than discouraged, from interesting themselves in various approaches to health through better nutrition."

Another frame that supplement manufacturers used as part of their meta-narrative was centered on the American *cultural/religious heritage*. During the Congressional Hearing in 1973, for instance, a supplement maker made the following public statement: *"You can't laugh these things off. Millions of Americans regard these ideas. Chinese medicine is not a*

[8] Studies show that actors employ narratives to pursue institutional work (Riaz et al., 2011; Zilber, 2007). One approach is to draw on 'meta-narratives' that exist at a society level, and thus resonate with many audiences (Suddaby & Greenwood, 2005; Zilber, 2009).

[9] The freedom of choice concept describes an individual's opportunity and autonomy to choose his own course of action and pattern of living, selected from at least two available options and is a highly embedded and resonant concept in the American culture. (Kemp, 1960).

joke. It has been practiced for thousands of years." Two years later, the President of the National Health Federation similarly said: *"This is who we are. Our Native Americans took these herbs to heal themselves. Why shouldn't we be allowed to?"* Overall, we find that by linking supplements and public's access to them to a metanarrative about the American cultural identity, supplement makers hooked supplement consumers to their cause. The next step was to activate consumers and widen the circle of influence, as explained below.

Activating consumers through rhetorical tools. After hooking consumers, supplement makers used rhetorical tools such as dramatization and urgency[10] to motivate them to act. To dramatize their situation, they portrayed the FDA as autocratic. For instance, in response to FDA's attempt in 1972 to require prescriptions for high-dosages of vitamins A and D, supplement makers published articles in magazines with dramatic analogies such as:

*"If the FDA has its way, one anticipates a clandestine organic underground in which pink-cheeked mothers meet shady characters in alleys. The ladies stealthily approach Vita-Pusher as their bright but shifty eyes peer furtively into the shadows for signs of the feds. "How are you fixed for E?" the health conscious mothers ask. "They busted my E contact," grumbles Vita pusher," but I can get you a fix of B-complex or enough wheat germ to last your kids for a week."(*American Opinion Magazine)

Similarly, in a Washington demonstration to "oppose the greatest tyranny within America today", National Health Federation's VP described FDA as "trying to set up a Volstead <Prohibition> Act, but with vitamins rather than liquor", adding that "when you take away a man's beer and his vitamins, you're in for some real trouble". Overall, this rhetorical tool helped supplement makers frame FDA's new regulations and product seizures as a severe attack on the public's freedom (see section before) in order to convince the consumers to act. The dramatization, particularly in public protests, also made their cause more visible to the general public and thus helped hook a wider audience than only supplement consumers.

[10] Rhetoric is the doing or practice 'of altering reality, not by the direct application of energy to objects, but by the creation of discourse which changes reality through the mediation of thought and action' (Bitzer, 1992, Green and Li, 2011). Rhetorical theory suggests that dramatic (i.e., pathos) arguments play an important role in explaining the need for audiences to act (Green, 2004; Martens et al., 2007; Suddaby and Greenwood, 2005; Waldron et al., 2016). Urgency has also been explored as a rhetorical tool to activate audiences (Bitzer, 1992) and a type of temporal work (Granqvist & Gustafsson, 2016), both with the basic principle of making individuals act through a sensation that a delayed response will have serious consequences.

Another tool to activate consumers was *urgency*, which they built into their rhetoric by emphasizing how citizens' freedom of choice could be taken away if they do not act. For instance, the legal counsel to the National Health Federation publicly asked for immediate action against FDA restrictions taking effect in October 1973: "*There is no health matter of greater urgency. On October 1973, I won't be able to buy vitamin A in high doses without a prescription. This is nutritional tyranny, not consumer protection.*" These rhetorical tools were heavily used throughout the supplements' struggle for recategorization (Table 3b).

Coordinating action through product's value chain. Once they hooked and activated the consumers, supplement makers organized the action through the products' value chain, i.e. health stores. For instance, when FDA required disclaimers on labels in the 60's, the National Health Federation (NHF) reached out to health stores, explaining how this would hurt them financially (e.g. "*Our business is under the threat of FDA's autocratic policies*") and provided pamphlets, letters, pens, which resulted in over 50,000 citizen letters to FDA and Congress. FDA Commissioner Goddard recalled: "*The diet food stores, who also tended to sell vitamins, mounted a campaign telling their clientele that the FDA was going to prevent vitamins from being sold over the counter.*" Certain pharmaceutical companies (e.g. Merck, Pfizer, Squibb) that sold supplements also joined this movement. Following the protests, FDA withdrew the proposed disclaimer in 1970. The story repeated itself in 1972, when FDA required prescriptions for high-dosages of vitamins A and D. The NHF again used health stores, this time to organize over one million letters to Congress. The effectiveness of this public campaign as soft power on Congress is evident below:

"The people were complaining that their vitamins were going to be taken away and Senator Hosmer wanted to help them." (Legal Aid to Senator Hosmer)

"Members of Congress invariably opened their remarks with a statement about the incredible amount of mail they had received and how constituents were incensed with the FDA's actions. Whether they personally advocated vitamin supplementation or not, the legislators were being told by voters in their districts to curb the FDA." (News Article)

In summary, we find that supplement makers used advocacy work to activate the Congress to override the regulator's category decision. We show that while overpowering a regulator requires hard power (e.g. laws) exercised by a higher state actor, activating this actor often involves soft power, most effectively exercised *through* the public.

FDA's Actions to Keep Supplements in the Drug Category

Category Work: Associating with target category

During this same period, the FDA attempted to *associate* supplements with drugs rather than food by redefining relevant attributes for categorization. While supplement makers associated supplements with food due to their ingredients, the agency argued that supplements should be categorized based on function, with comments like "explicit claims related to prevention or treatment of specific disease conditions render a product a drug." What is noticeable in FDA's communications to justify its categorization is its heavy use of scientific evidence. In 1966, when proposing stricter rules, Commissioner Goddard explained: "*We read the scientific literature and we go to the best scientists in the United States. This is based on careful scientific evaluation."* Similarly, in 1973, FDA commissioner Alexander Schmidt announced: "*The new regulations are based on the best and broadest scientific evidence*."

Maintenance work: Educating, Policing, Deterrence

We find that the biggest difference between supplement makers and the FDA was that while supplement makers used advocacy work to activate the public to pressure Congress, the FDA engaged in practices to *educate, police* and *deter* the public from using supplements. To educate the public, FDA proposed to put disclaimers on supplement labels during the vitamin boom in the 60's. They also invited the American Medical Association to jointly launch the

Medical Quackery Campaign of 1961[11]. Commissioner Larrick made public statements arguing that consumers were misled by the industry and needed to be educated:

"Consumers lack the information they need to make reasoned choices; consequently are misled into thinking that their diets are inadequate. This ignorance induces consumers to buy products loaded with many times the daily requirement of most, if not all, of the nutrients in the belief that each ingredient makes a significant addition to his customary diet."

As noticeable in this quote, FDA's statements portrayed the consumer as ignorant and easily manipulated, which was interpreted as a "paternalistic attitude", "big brotherism" and "daddy-knows-best arrogance" in public letters to Congress (Apple, 1996). This image was exacerbated by FDA's *policing* and *deterrence*[12] tactics (Lawrence and Suddaby, 2006). As an example of policing, the FDA engaged in many product seizures, which the agency summarized in a 72-page document during congressional hearings for the Proxmire bill. The FDA also used its power to *deter* the public from using supplements, for example through the 1968 proposal to require disclaimers on dietary supplements or the 1973 proposal to require prescriptions for high-dosages of vitamins A and D. Table 4 summarizes the evidence. Overall, educating the public rather than generating their advocacy, combined with policing and deterrence made the agency appear arrogant and coercive, helping supplement makers' advocacy work to turn the public and Congress against the FDA, as explained further below.

Phase 2: Creation of a New Regulatory Category

As described in the chronology, the FDA remained largely inactive following the Proxmire Amendment, but was called back into action after the public crises in the 80's. Once the agency started to regulate supplements more strictly through the food additives subcategory and labeling restrictions, supplement makers saw the only solution to circumvent

[11] We observe that the only advocacy that the FDA tried to generate was from doctors and pharmaceutical companies. While the American Medical Association supported FDA's education campaign, the FDA took a hit from pharmaceutical companies, 12 of which, including Abbott and Pfizer, sued the FDA before the Proxmire Amendment to not implement its proposals before holding hearings on the issue. The split of pharmaceutical companies over supporting or opposing the FDA significantly affected the regulatory categorization of supplements.

[12] Policing ensures compliance through enforcement, auditing and monitoring while deterring establishes coercive barriers to institutional change (Lawrence and Suddaby, 2006).

FDA's regulation in creating a new category where the FDA was not the only evaluator. Their work to create an entirely new category involved many of the actions described in Phase 1, which we discuss briefly, and some unique actions, which we elaborate on below.

Supplement Makers' Efforts to Move into a New Category

Category Work: Disassociating from Category and Evaluator, Selective Representation

We find that just like they dissociated from the drug category through relevant category attributes in the previous phase, supplement makers theorized the necessity for a new category by *dissociating themselves both from drug and food categories*. In order to dissociate themselves from food, they used function-based arguments, following the same logic used by the FDA in the previous phase. For instance, Robert Caleb of Herb Research foundation dissociated from food in the following public statement in 1993:

"There are sound reasons for distinguishing the regulation of dietary supplements claims from those of conventional foods. I would say the major difference between conventional foods and dietary supplements is that by large, people understand why they eat food, but require more education about the potential benefits of dietary supplements. In addition, dietary supplements are optional components of the diet, while foods are consumed to sustain life. There are many examples of nutrients, herbal products and other supplement ingredients which appear to offer benefits, only at levels higher than normally found in conventional food. This is the key scientific basis for distinction between these two categories of products."

In order not to get close to the drug category while dissociating from food, supplement makers emphasized that supplements were natural products but taken at much higher doses, which made them unlike anything else, with statements such as:

"FDA defines foods as "consumed primarily for their taste, aroma or nutritive value." One possible result of such a forced definition is that FDA may feel it necessary to limit the amount of a vitamin that can be in a pill, because true foods contain only that amount. Or FDA may feel it necessary to define any supplement with more than a "food" amount as a drug, therefore requiring extensive and expensive procedures for some things that have been in wide common use for decades or centuries. Or FDA may define "nutritive value" as limited to functions identified in the early part of the century, such as promoting growth, and any amount more than necessary for those functions as a drug requiring drug regulation. But our understanding of nutrient functions and levels for optimal health are expanding rapidly. Those older definitions are no longer sufficient to describe the value that may be obtained from more-than-minimal amounts of natural substances (Dr. Gladys Block, 1993 hearing).

In 1993, President of the United Natural Products Alliance similarly disassociated supplements from both categories as follows: *"The basic principle of this moratorium was that dietary supplements aren't food additives, they aren't drugs and they need to be defined*."

Since a key reason for the new category was to free themselves from the sole authority of the FDA, supplement makers also dissociated themselves from the FDA in two ways. First, they argued that supplements were a breakthrough product that the FDA did not have experience with and therefore could not regulate appropriately with statements such as:

"The reason the FDA regulations pose potential problems is due to the fact that (the agency's) area of expertise has been synthetic drugs and traditional foods. But these items are not new drugs. They are medicines derived from food sources…We must define what a dietary supplement is if it is different from strictly food or drug." (Rita Bettenburg, Foundation for Innovation in Medicine, food labeling news, specialized news journal)

"I wonder if it may not be time to consider removing dietary supplements from FDA's purview altogether, so that a regulatory structure appropriate for supplements themselves can be developed, free of the historical baggage and existing constraints". *(*Dr. Block, 1993 hearing).

Supplement makers also used FDA's relationship with the pharmaceutical industry as a bias to further *dissociate from the FDA as category evaluator*. Citizens for Health stated that the FDA's proposed rules were "an obvious attempt to protect the interests of the prescription drug industry". The NHA warned similarly that it was "an international conspiracy by the drug industry to eliminate preventive therapy" while a prominent lawyer for supplements, Jonathan Emord, recalls how they kept saying that FDA was "a captive of the industry".

Overall, dissociation from both the category and its evaluator fits a larger theme of innovation in the public interest that disrupts the current system. To emphasize this, supplement makers made frequent references to a USDA study from the 60's that found that Americans had severe nutritional deficiency with statements like *"Vitamins are the answer to today's malnutrition epidemic."* They also made references to the alternative medicine movement developing since the 70's with statements such as:

"The American health care system has been characterized as a 'disease treatment system' because of the conspicuous absence of approved preventive medicines... After over 50 years of drug regulation, the FDA has not approved a single over-the-counter drug for internal use in the prevention of any major disease. FDA never even established a category in which preventive medicine products could be considered...Millions of [Americans] are willing to spend their own resources on protecting their heath through diet, exercise and supplements. They are not charging their herbs and vitamins to insurance companies or Medicaid. They are taking personal responsibility for their health care and attempting to practice preventive medicine, just as they should. Under the current [pre-DSHEA] regulatory system, this can be hard to do." (Robert S. McCaleb, Herb Research Foundation)

We note that the target category in this period was a new category for 'dietary supplements', which did not resonate with the public as a label. Thus, supplement makers did not use labeling strategies to associate themselves with the target category, but for *selective representation* to fuel their advocacy work. While they referred to themselves as 'food' in many statements in the first phase, they referred to themselves as 'vitamins' in the second phase[13] (e.g. *"Write to Congress today or kiss your vitamins goodbye"*, *"For God's sake, we're talking about vitamin C"*). Vitamins were not only the most well-known but also the most innocent supplement, particularly compared to amino acids and protein powders. This helped them dramatize their situation to activate audiences, as discussed further below.

Advocacy Work: Lobbying state actors, hooking-activating-coordinating consumers

Moving into a new category had many elements of advocacy work similar to those in the first phase, but at a higher level of intensity (e.g. more dramatic analogies, larger public campaign and lobbying efforts). Like before, supplement manufacturers activated state actors both directly and indirectly. First, they reached out to Senator Hatch, whose state Utah was the heart of supplement manufacturing and who personally had a significant investment in a Utah supplement distributor. Over 80 supplement makers contributed to Hatch's re-election campaign, urging him to protect supplements. In 1992, Senator Hatch obtained a one-year

[13] We also observe the use of the vitamin label from time to time in the first phase, but this may be partially due to the fact that FDA directly targeted vitamin products then through warnings on labels and restrictions to higher dosages of Vitamin A and D. On the other hand, in the second phase when there was a boom of protein powders and amino acids, and particularly after the L-tryptophan crisis, there was a strategic and more inclusive labelling of the whole category through the least controversial label, vitamin.

moratorium in Congress on the application of FDA's labeling laws, which gave supplement makers additional time for their effort to activate Congress for long term law change.

During this time, supplement makers also engaged in a wider lobbying effort such as a lobbying day in 1993, when a group of merchants visited Congress. NNFA arranged meetings, lobbying kits, and a seminar to prepare them for meetings with congressional staffers. According to public records, the industry spent over $2 million on lobbying. To convince senators, supplement makers mostly used economic sustainability arguments such as:

"Mr. Chairman, companies like mine need your help. The industry needs your help. Our very survival is at stake if FDA is allowed to continue these Alice in Wonderland[14]-like theories to arbitrarily keep our products off the marketplace" (Sidney Tracy, Traco Labs, hearing)

"Congress can prevent the FDA from dealing a crippling blow to the small businesses of the dietary supplement industry which provides 340,000 jobs" (President NNFA, hearing)

However, as in the previous period, supplement makers' critical move to overpower the FDA came from using soft power on Congress *through* consumers.

Hooking consumers through meta-narratives. Supplement makers again linked their cause to a meta-narrative on Americans' cultural identity (Table 3b). For instance, against FDA's stricter labeling regulations, they urged consumers to protect their freedom of choice by sending letters to Congress, stating: *"FDA's bias against preventive medicine and the dietary supplement industry will take away the American citizen's health care freedom of choice."* They also continued to frame supplements as part of American cultural heritage with statements such as *"Supplements are part of our spiritual heritage because medicinal herbs are mentioned in the Bible. FDA's treading on the essence of democracy and the essence of a spiritual legacy."* Referring to this meta-narrative, Senator Waxman said: *"It was a very clever campaign, one that manipulated certain beliefs that many people have."*

[14] Associating FDA policy with Lewis Carroll's Alice in Wonderland where the Queen says 'Sentence first; verdicts afterwards'.

Activating consumers through rhetorical tools. In this period, FDA's product seizures following the E-Pherol and L-Tryptophan crises gave supplement makers an opportunity to *dramatize* themselves as victims against an excessively authoritative regulator as the antagonist[15]. They used analogies like FDA as dictator, and its Commissioner as the 'Diet Czar', "arbitrarily barring citizens from freely employing and consuming such dietary supplements". In 1994, the Life Extension Foundation established the FDA Holocaust Museum in its headquarters with exhibitions consisting of books, articles and videos about life extension, as well as placards equating the FDA to Nazis. The museum also had a website, where they documented the "*70-year reign of terror that the FDA had perpetrated against Americans*". Another great example of dramatization is the commercial in 1993, where Mel Gibson said to Special Forces arresting him: "*Hey. Guys. Guys. It's only vitamins. Vitamin C, you know, like in* oranges?" Supplement makers also used *urgency* arguments to activate consumers. For instance, they put TV and radio announcements in 1992, warning consumers: "*If you don't act, your rights to access to these products will be taken away.*"

Coordinating action through product's value chain. In this period, supplement makers again used health stores to coordinate a public campaign. In 1993, they used health food stores to invite consumers to the NNFA rally in Las Vegas, which raised $200,000. Communication to stores said "*If we fractionate, it's all over. Our strength is in activating all 100 million consumers*" or economic sustainability arguments like:

"The effect of the regulations on the supplement industry is likely to be devastating. Half of the familiar herb and supplement products could disappear from store shelves, putting many distributors and retailers out of business. We can't make money selling beans and potatoes!" (Jerry Sealund, Supplement Maker, California)

Once on board, health stores set up "political action centers". A GNC executive recalls:

[15] The 'archetype narrative frame' has been explained as framing oneself as working against an antagonist or obstacle to build legitimacy or create dramatic tension (Cooren, 2001; Golant and Sillince, 2007).

"GNC and Tree of Life funded the creation of the Save Our Supplements sign-up center. It was a freestanding information stand that encouraged customers to read the facts and send a letter to their congressman about the issue. Between GNC stores and stores that Tree of Life sold to, there were around 4,000 of those sign-up centers. It was a very big grassroots effort to "save our supplements."

In 1993, 6,000 stores organized a "blackout" day, covering supplements with black fabric and refusing to sell them. They followed up with what became the second largest letter-writing campaign (2.5 million) in U.S. history after Vietnam War. Communication material stated:

"Company and store owners should explain to employees the importance of grassroots communications to congress. Retailers must immediately begin asking customers to call Washington and tell congress to keep supplements available. Write to Congress today or kiss your supplements good-bye!"

Overall, supplement makers created a new category through soft power on Congress, directly through lobbying and indirectly through hooking, activating, and coordinating consumers.

FDA's Actions to Keep Supplements within the Food Category

Category Work: Associating with target category

While supplement makers were working to create a new category, the FDA worked on maintaining its strict approach to regulation by putting supplements into a sub-category within food with more restrictions (Table 2). For this, the FDA again redefined the relevant attributes for categorizing, this time focusing on component rather than function: the agency argued that since the gelatin in the supplement capsules was categorized as food, any ingredient added to it would be a food additive, which would require pre-market approval.

While categorizing the supplements, the FDA continued to use scientific arguments. In 1993, for instance, FDA Commissioner Kessler, said: *"We need to give consumers a meaningful choice, one based on science, not salesmanship"*. A Congressional aide in 1994 explained FDA's approach: *"They never understood the politics of the movement because their mind-set has been: 'This is how science operates'".*

Educating, Policing, Deterring

As in the previous period, FDA focused on educating the public, this time through the "anti-quackery" educational campaign. While supplement makers used advocacy to activate the public and subsequently the Congress, the FDA mainly used advocacy to generate funds for *educating* the public. After E-ferol crisis of 1983, in 1985, the FDA engaged the Pharmaceutical Advertising Council (PAC) to receive funds from the pharmaceutical industry for the campaign. Mark Blumenthal, Director of the American Botanical Council described:

"The PAC and the FDA also issued a joint statement addressed to the presidents of advertising and PR agencies nationwide asking them to cooperate with a joint venture anti-fraud and quackery campaign."

To solicit the industry support, the FDA used economic sustainability arguments such as:

"Pay careful attention to what is happening with dietary supplements in the legislative area…If these efforts are successful, there could be a class of products to compete with approved drugs that are subject to less regulation than approved drugs…the establishment of a separate regulatory category for supplements could undercut exclusivity rights employed by holders of approved drug applications." (FDA Deputy Commissioner Adams, 1993)

Many food corporations (e.g. Nestle USA) and the National Food Processors Association publicly supported the FDA, but pharmaceutical companies were split, with a considerable number already producing supplements and thus not supporting the agency[16].

The FDA again used *policing*, particularly after its legitimacy was in question due to the E-ferol and L-Tryptophan crises. They formed a special branch called the "Health Fraud Unit" and dramatically increased product seizures. In 1992, a police raid in a small medical practice in Washington State that gave B12 vitamin injections was caught on camera and made national headlines. After the 1993 "proposed rulemaking" announcement, the FDA seized supplements worth over $1million just in Nevada. The FDA continued its *deterrence* tactics as well. Using the Nutrition Labeling and Education Act (NLEA) of 1990, the FDA blocked many supplements arguing that food products could not make health claims (See

[16] We also see evidence in this period that several public interest groups supported the FDA. For instance, a collection of groups sent letters to Congress asking FDA's enforcement powers not to be restricted. Bruce Silverglade, of the Center for Science in the Public Interest, referred to the supplement campaign as "the big lie of 1993." Dr. Sidney Wolfe, of The Public Citizen, a consumer advocacy group, said: *"This is a drug industry. The difference between large doses of vitamins and over-the-counter [drugs] is non-existent. Exploitation of genuine concerns people have for their health [by promoting] vitamin pill–popping solutions is no better than . . . fraud."*

Table 9 for claims that the FDA contested). In the 1993 Congressional hearing, Senator Hatch quoted that FDA rejected 75% of health claims made by supplements. In addition, he stated that "the FDA process for approving health claims was too cumbersome and results in delays which work to the detriment of good health in America". FDA's reduction in daily allowances printed on labels of 14 most popular vitamins, as well as its plea to PR agencies to not publish supplement advertising also serve as examples of deterring vitamin usage among the public.

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Overall, FDA's scientific approach, focus on educating the public rather than generating advocacy, and its policing and deterrence tactics allowed supplement makers to portray the regulator as arrogant and aggressive, and themselves as victims. In our interview, lobbyist Tony Podesta described: "*They issued statements to reach the public and there were couple of groups on the side of the FDA but they did not have a grassroots movement.*" In the next section, we describe the contributions of these findings to extant theory.

DISCUSSION

This paper uncovers *regulatory categorization*, which is a critical process for firm performance and survival as it sets the legal terms and conditions under which a product is made and distributed (Funk & Hirschman, 2014). We show that unlike product categorization, regulatory categorization is a contest against a powerful state authority, but involving many actors from individual consumers to industry incumbents and other state actors. In the spirit of our topic, we categorized our contributions to extant work as first, uncovering *strategic categorization and its micro mechanisms* in the regulatory space - with contributions to institutional work and corporate political strategy literatures, and second, understanding *regulatory categorization as a multi-player contest*, with the perspectives and actions of various players that have largely been overlooked by previous studies.

1. Micro-Mechanisms of Strategic Categorization

a. The Role of Power and Advocacy Work in Regulatory Categorization

This paper uncovers how both firms *and* state actors use strategy to influence the process of regulatory categorization (Figure 2) and how in this contest to disrupt / maintain a product's regulatory category, power plays a major role. While recent work hints at possible disagreement between different (product) category audiences due to varying principles for assessing causality and that the outcome may be influenced by the power position of these actors (Granqvist & Ritvala, 2016), most studies on categorization focus on how firms signal category membership (Granqvist et al., 2013; Zhao et al., 2013; Vergne 2012), but not what happens after category membership has been achieved. Answering a recent call by Grodal & Kahl (2017), our study sheds light on the evolution of regulatory categories, revealing how power contests between firms and regulators play out. It shows that categories not only create relations of power within a field between different actors (Brown *et al.* 2012) but like other types of institutions (Rojas, 2010), they themselves are created through power processes between firms and different actors. More specifically, we posit that for firms, fueling a power contest between state actors is a key mechanism of strategic categorization in the regulatory space. Extant work in corporate political strategy typically focuses only on legislators and firms' unidirectional efforts to influence them, while the multiplicity of state actors and the power struggles between them are largely overlooked. Our study shows that even a powerful actor such as regulator can have its categorization decisions overturned and its sole authority over the matter challenged by other state actors that are activated by firms through advocacy.

A critical component of this finding is our discovery of the role of hard versus soft power in overpowering the regulator. Scholars distinguish *hard power* which is based on coercion, direct rewards, and extensive resource deployment to force others' behaviors, from *soft power*, which is based on subtle influence mechanisms that cause others to willingly behave in ways that benefit the focal agent (Nye, 2004; Santos and Eisenhardt, 2009). In their

recent review of the power construct in institutional studies, Lawrence and Buchanan (2017) similarly identified *influence* and *force* as key constituents of institutional agency, but did not expand on which actors may use them, when and how, to achieve institutional objectives. Our paper shows that overpowering a regulator often comes down to hard power, or force (Lawrence and Buchanan, 2017), in the form of new laws, but such hard power is often assembled through soft-power or influence on other audiences. In their recent review, Grodal and Kahl (2017) suggested that it is often difficult for actors in low-power positions to participate in a discourse to influence category audiences. Going beyond discourse, our paper shows how, even in cases where categorization is in the hands of powerful state actors, less powerful actors such as small firms can influence the process by generating advocacy among other category audiences, as further explained below.

Our study reveals that a critical component of winning the categorization contest against the regulator was advocacy work to activate Congress, both directly and indirectly through soft power. Congress has power on other parts of the government, e.g. regulators, through laws, committees, etc. At the same time, private parties, e.g. citizens and companies, have power over Congress through votes and donations that fund campaigns, as laid out by studies of corporate political strategy (Schuler, 1996; de Figueiredo & Kim, 2004; Baumgartner et al., 2009). We show that supplement makers exercised soft power through narratives and rhetorical tools to engage a set of actors that hold power over Congress: the public. The activation of Congress through the public expands the concept of *advocacy work*, first put forward by Lawrence and Suddaby (2006) as a form of institutional work used in the creation of new institutions. Since then, other concepts such as political work (Perkmann and Spicer, 2008), relational work (Hampel et al., 2015) and engaging work (Slager et al., 2012) have all been used to highlight different aspects of gaining supporters to bring about wide-scale change, but without specifying how each actor is influenced. Rather than adding a new

concept, we expand *advocacy work* beyond the creation of institutions to show its critical role to generate *any* institutional change involving state actors. Going beyond definitions, we also unpack advocacy work in the regulatory space by showing how change can be realized through a combination of hard and soft power tactics targeting different audiences.

In the unpacking of advocacy work, an important contribution we make to extant literature is the identification of the specific mechanisms of advocacy work - *hooking* through meta-narratives, *activating* through rhetorical tools, and *coordinating* action through the value chain - to exercise soft power on Congress via consumers. In addition to identifying these micro-mechanisms of advocacy work, we suggest that their *sequence* is critical. To start with, getting the consumers interested in the cause by linking it to a larger cultural frame (Suddaby and Greenwood, 2005; Steyaert, 2007; Zilber, 2009) is an important first step to "catch attention". However, interest or attention does not equal influence if the interested actors are not motivated to act (Vaccaro and Palazzo, 2015). At this point, our findings suggest that rhetorical strategies of dramatization (e.g. through an archetypal protagonist/antagonist frame, Cooren, 2001; Golant and Sillince, 2007) and urgency (Bitzer, 1992; Granqvist & Gustafsson, 2016) can help intensify consumers' emotional reaction to the issue and increase their likelihood of acting quickly. In addition, dramatization helps catch public's attention and widen the target audience from consumers to the general public. Finally, engaging the products' value chain can effectively *coordinate* the action and direct it at the right target (e.g. Congress) using firms' direct access to consumers. Overall, this novel sequence emphasizes the role of meta-narratives involving cultural values, rhetorical tools, as well as activating other actors (e.g. product's value chain) in generating advocacy among public.

Overall, our study follows earlier calls (e.g. by Mitchell et al., 1997) to pay attention to power differences between various stakeholders, by highlighting that advocacy work to influence a target audience requires activation of other audiences a thoughtful selection of

each audience in the right sequence due to the linkages between them (e.g. effect of point of sale stores on consumers, public's effect on Congress) and targeted arguments to activate each. This view emphasizes the exercise of power *through* other actors (Fleming and Spicer, 2016). More broadly, our study contributes to building greater awareness of power in institutional theory (Lawrence, 2008; Munir, 2015). While researchers acknowledge power as a catalyst of institutional processes, little is known about the distributed nature of power between those engaged in institutional work and how these affect their actions and strategies (Rojas, 2010). We address these gaps in the particular setting of firms versus regulators.

b. Category Work and the Creation of Regulatory Categories

Our findings also highlight the role and mechanisms of category work within regulatory categorization. We define category work as efforts to influence the defining attributes, boundaries and membership of a category and show their importance in cognitively preparing critical audiences for category change even if the change requires new laws and regulations, like in the case of regulatory categorization. We unpack category work through the mechanisms of dissociating from the current category, associating with the target one and selectively representing the category members. Granqvist et al (2013) put forth *dissociating* as a strategic practice to distance from a category label by denouncing any connection in names, rhetoric, or practices. In addition to labels, we show the existence of a deeper level of dissociation *and* association based on a product's relevant attributes for categorization and how these attributes can be used strategically by opponents in a categorization battle.

In addition, we find that while labels serve actors to associate themselves with extant and well-known categories (e.g. food), they are less helpful in new regulatory category creation as the name of the new category may not yet be resonant. While actors often try to establish the name of a new product category among key category audiences for adoption and sales purposes (Granqvist et al, 2013), this is less necessary for regulatory categorization as

the legal label of a category typically matters much less to the users of the product. We find that in these cases, labeling, particularly through prototypes, can be used for the *selective representation* of the category members. Extant literature highlights using prototypes – i.e. the most representative or central member of the category according to a given audience (Rosch & Mervis, 1975;) as a natural way for audiences to categorize new products and services (Verne & Wry, 2014). Our findings suggest a more strategic use of prototypes. Specifically, choosing not only the most salient, but also the least controversial member as a label helps category members selectively represent themselves and manipulate public perception of the category for the purpose of generating advocacy, e.g. through dramatization.

Our study also answers previous calls (e.g. Suddaby, 2010) for institutional theorists to explore category origination versus reification. We contribute to this research (e.g. Durand and Khaire, 2017) by illustrating how regulatory categories are not only created by powerful incumbents but also by peripheral actors, to achieve instrumental goals. We find that supplement makers used goal-based categorization while the regulator used causal-based categorization (Granqvist and Ritvala, 2016) relying on professional knowledge. In addition to contributing to categorization research by contrasting various uses of categorization by opposing actors, this contributes to institutional entrepreneurship and change (e.g. Greenwood, et al., 2002; Schneiberg & Bartley, 2001) by illustrating that firms not only attempt to change the rules and laws that they are subject to, but also the institutional actors that evaluate them.

We also find that creating a new regulatory category requires disassociation from *both* the extant category and its evaluator through a frame of innovation that renders the category and the evaluator obsolete. Within this context, opposing a regulator for standing against innovations in the public interest[17] both dissociates the regulator as appropriate category

[17] Recently, studies have begun to identify how the public interest concept (Pigou, 1932) can be open to interpretation during the regulation of new technologies (Gurses & Ozcan, 2015). This study shows that even a non-technology product can be framed as an innovation in the public interest to effectively break away from the extant regulatory framework through public support.

evaluator and helps with advocacy work to activate the public. Extant work by Durand and Khaire (2017) differentiates between *category emergence* due to the insufficiency of the current category system to accommodate an innovation versus *category creation* for strategic reasons. Our findings provide a nuance to this work by showing that actors can mask strategic category creation with a frame of innovation to legitimize the need for a new category like in Durand and Khaire's (2017) case of category emergence. Finally, we show that in the regulatory space, both category change and new category creation can be tools to overpower hostile state actors. While requiring more effort, creating a new regulatory category allows firms to reset category evaluators whereas moving to a different category under the same regulator carries the risk of unfavorable recategorization, as evident in our case.

2. Regulatory Categorization as a Multi-Player Contest

Another significant contribution of our work is to show the regulatory categorization process as *a contest between various players*. Following previous calls by scholars to uncover political contestation during categorization (Durand et al, 2017; Grodal and Kahl, 2017) and to consider the various contradictory and complementary institutional work done by the different actors involved in institutional processes (Delbridge and Edwards, 2008), our findings show that regulatory categories are neither decided solely by a regulator, nor shaped by regulated firms without resistance: they are the outcome of a contest between the two, but involving multiple other category audiences (Figure 2). Having already identified the strategic categorization efforts of firms and the critical role of legislators, consumers, and the product's value chain, we now turn to the efforts and limitations of the other actors in the process.

Regulators. Our findings contribute to a more nuanced portrait of regulators as actors with certain tendencies and limitations rather than boundless, absolute authorities that singlehandedly impose or resist change. An important characteristic of regulators is that they largely consist of subject specialists and experts who have a predominantly scientific

approach to categorization. Extant work by Hiatt and Park (2013) documents the importance of following scientific procedures and techniques for regulatory actors to maintain procedural legitimacy. Our story highlights the flipside of such strong focus on scientific procedures for regulatory actors. We show how it can lead them to overlook the importance of pragmatic legitimacy, i.e., maximizing the utility of key audiences (Suchman, 1995), and soft power, e.g. convincing consumers by appealing to emotions and cultural values, and to maintain legitimacy and authority through hard power tactics instead. In addition, the fact that members of regulatory bodies are typically appointed rather than elected may contribute to regulators dictating rather than attempting to convince the public. Our story shows that these characteristics of regulators can in turn enable regulated firms to appeal to the public and subsequently to other elected state actors to influence regulatory categorization in their favor.

Category Incumbents. Finally, we also identify the critical role of category incumbents during regulatory categorization. Zhao (2005) depicted how incumbents strive to control the (product) categorization system to consolidate their position. We find that in the categorization of new products and services, category incumbents may not all show the same response as they may be split over whether to diversify into these new sectors or resist their growth. This can be an important opportunity for entrepreneurial market entrants to diffuse opposition power and shape regulatory categorization. Theoretically, this finding provides a nuance to the influence of industry incumbents on regulators (e.g. through 'revolving doors', Eckert, 1981; Hillman and Hitt, 1999) by showing that incumbent firms' different reactions to the emergence of a new market may interfere with their unified support on regulators' policies.

By identifying the perspectives and actions of these different actors, our findings show regulatory categorization as a multi-player contest where firms and regulators attempt to disrupt or maintain the regulatory category respectively, dividing category audiences into two camps in the process, with some audiences split between the camps depending on their

economic benefit. Previous studies have shown framing contests inside organizations (Kaplan, 2008) and between industry entrants and incumbents (Gurses and Ozcan, 2015). We uncover a unique contest that takes place between regulators and firms and entails soft power – and the limitations thereof - to engage the public for influencing the regulatory process. Echoing the work of Lounsbury and Rao (2004) and Zhao (2005), we highlight the political nature of categorization and go a step further to unpack this process in the regulatory space.

CONCLUSION

This paper explores *how regulatory categories are determined through the strategies and interaction of firms, regulators and other category audiences.* In uncovering this process, our findings contribute to extant literatures on institutional work and corporate political strategy, which have largely remained independent despite dealing with many of the same issues. Our theoretical framework also connects categorization and institutional work literatures by highlighting the importance of institutional work for both state and non-state actors during regulatory categorization. We contribute to both streams of literature by examining their processes of focus through the much-needed power lens, paying attention to the power differentials between the different actors and their various tactics to gain power.

A limitation of our study is its setting in a single industry where, in addition to the mechanisms we identify, the general political and cultural climate at the time might have contributed to the outcome. For example, the alternative medicine movement in the 70's and 80's may have made actors practicing in adjacent fields (e.g. acupuncture, chiropractic) sympathetic to the dietary supplement movement and helped widen the political support. It is also noticeable that the FDA became particularly active after its legitimacy was questioned following the numerous deaths by supplements in the 80's. In a more liberal political environment and in the absence of legitimacy crises affecting state actors, firms may not need such a society-wide campaign to obtain more favorable regulation. Finally, a boundary

condition for our story is that our setting has immediate implications for individuals' health and well-being, which makes the public particularly susceptible to heightened emotions. Future studies should consider which other issues may become central during regulatory categorization in other markets (e.g. energy or broadcasting) that have less dramatic implications for the society at large.

Despite the specific nature of our setting, however, our findings can help us understand current dilemmas such as those regarding peer-to-peer platforms where firms (e.g. Uber, Airbnb) are advocating the creation of a new category ("sharing economy") that would involve the rewriting of many laws and regulations (e.g. taxes, employment, insurance). For instance, during the California hearings in 2013 where "transportation network company" category was discussed, Uber similarly engaged in advocacy work, organizing large groups of supporters and drivers to attend the hearing and send emails to the California Public Utilities Commissioner to support "consumer choice" and "innovation that makes cities safer, more affordable and better connected" with the successful outcome of creating this new category. On the other hand, the case of e-cigarettes earlier provides a counter example where lack of ability to engage the public for protecting the public interest might have contributed to unfavorable regulatory categorization.

In unpacking the process of regulatory categorization in these newer settings, scholars should further investigate the role of hard versus soft power tactics in the process, as well as how power may be distributed differently among category audiences, e.g. which category audiences, in addition to regulators/legislators, may be key evaluators in other settings, and whether these actors are similarly limited in their use of cultural meta-narratives and soft power like the regulators in our case.

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Figure 1: Analytical coding process

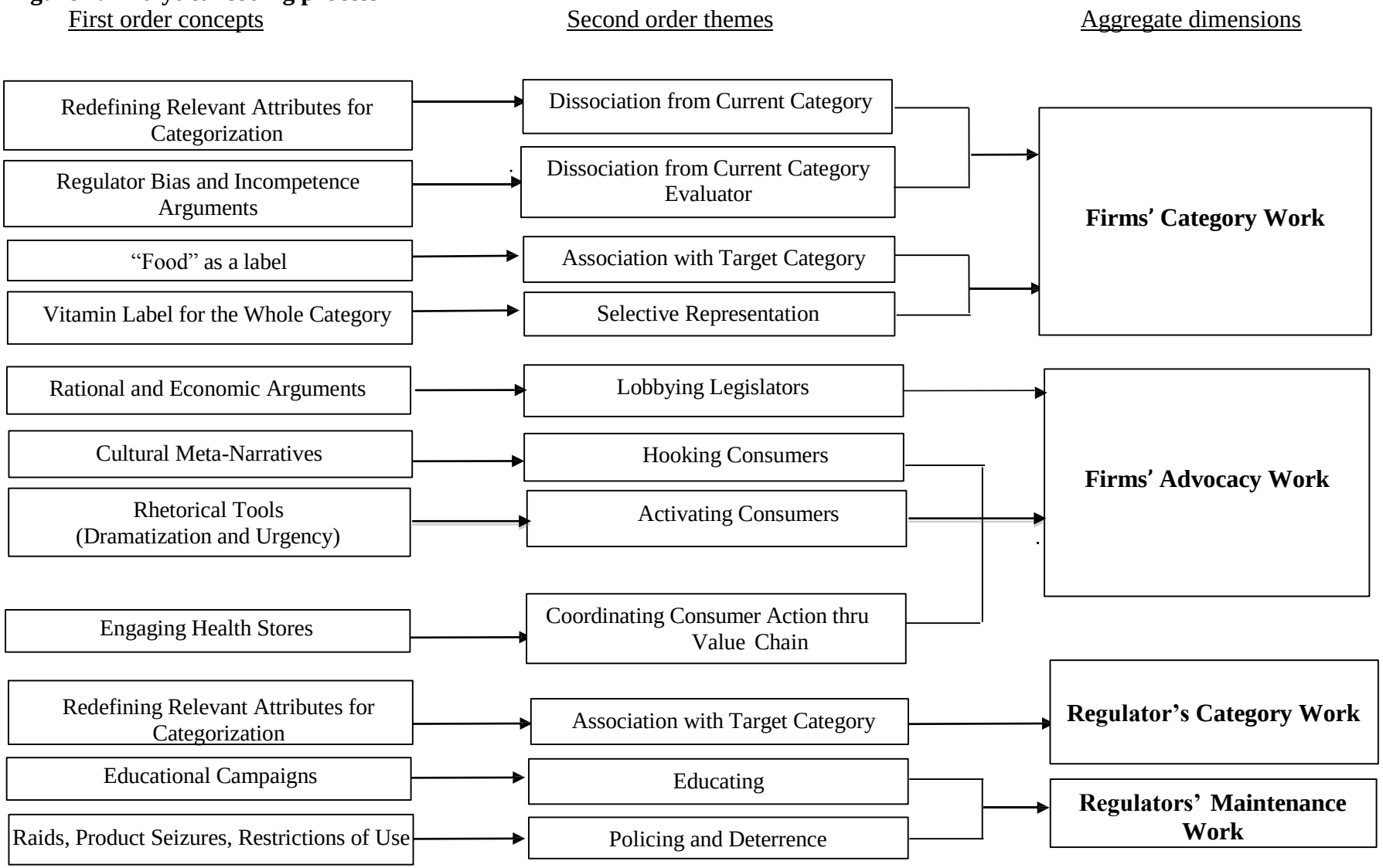

Figure 2: Theoretical Framework for Strategic Categorization in the Regulatory Space

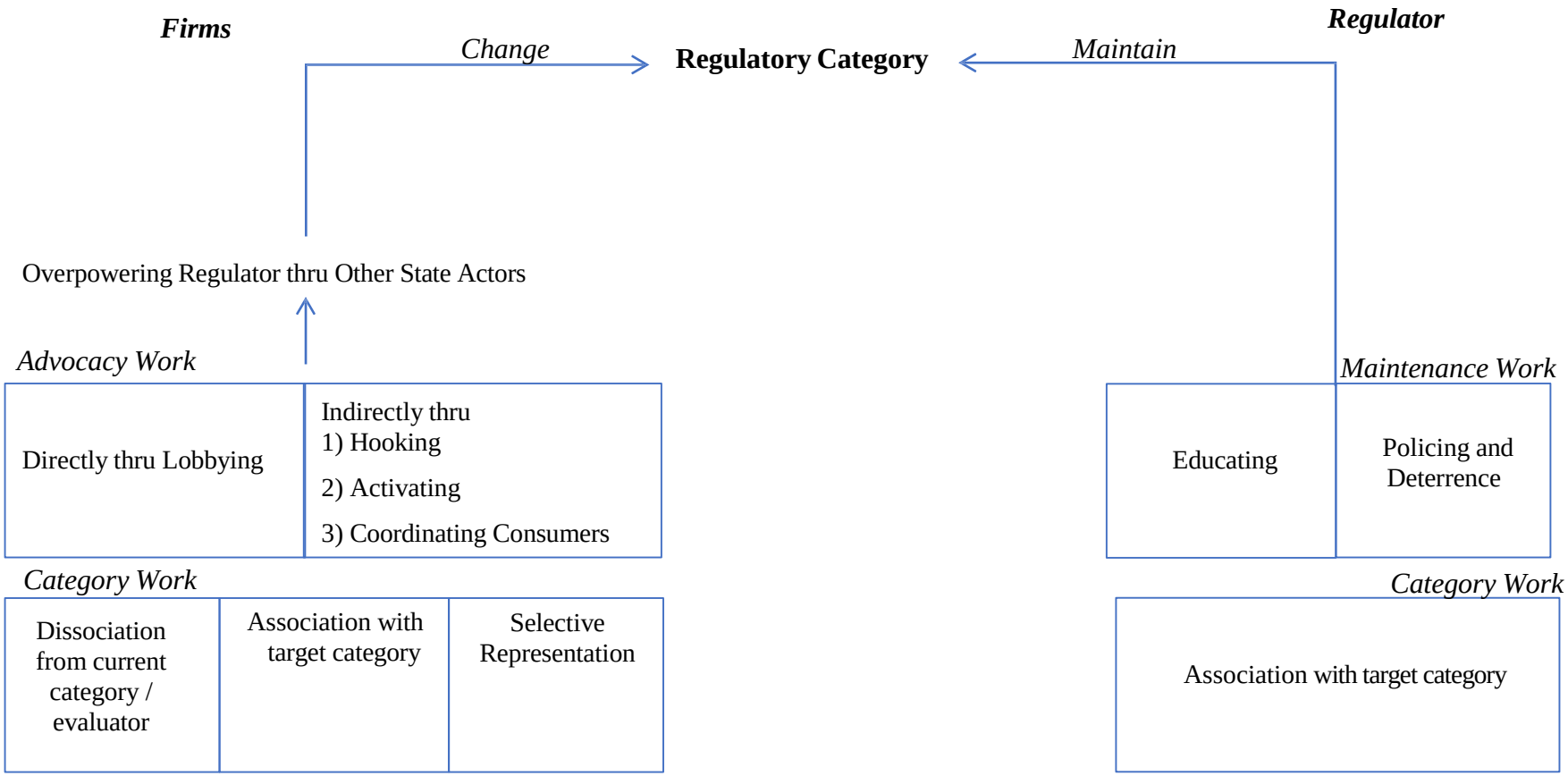

Figure 3: Types and Drivers of Firms' Strategic Categorization in the Regulatory Space

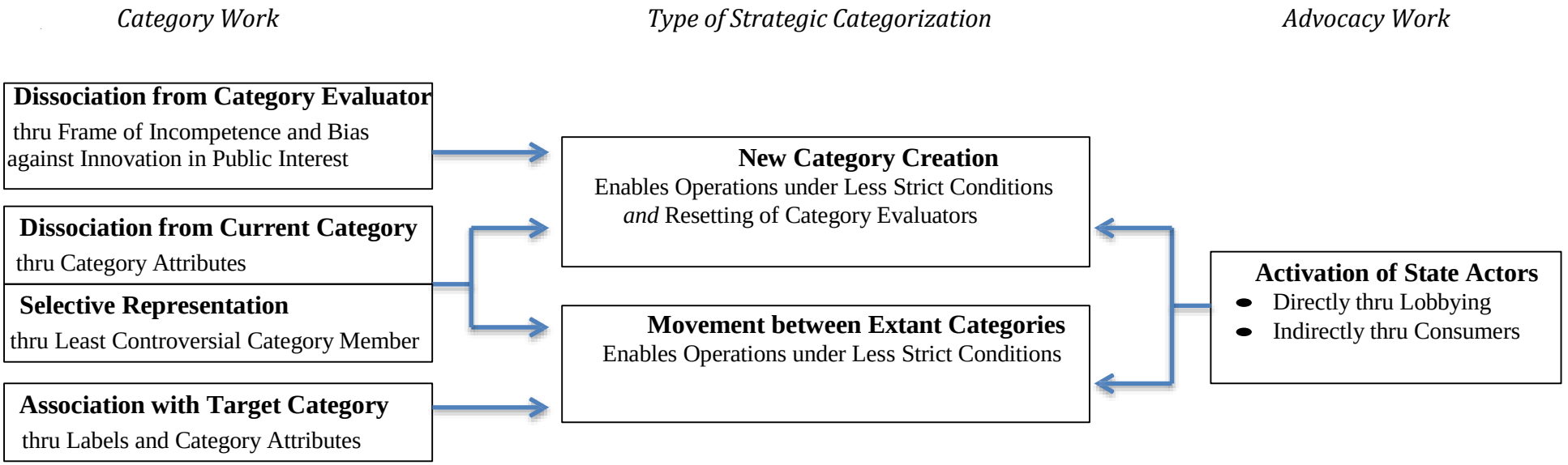

Figure 4: Overview of Key Events in the Regulatory Categorization of Dietary Supplements

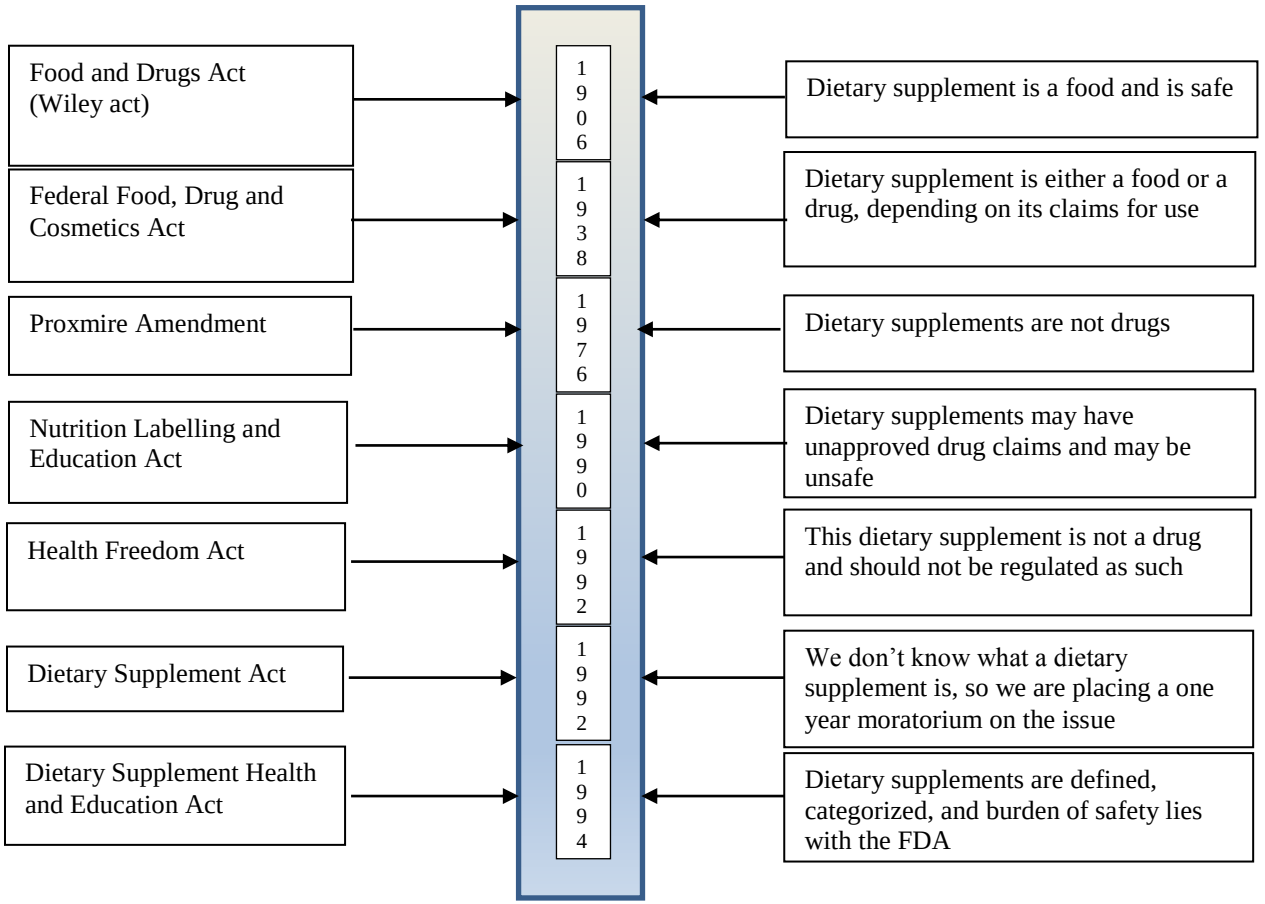

Table 1: Data sources

Type of data	Sources	Example quotes from the source
Specialized news journal articles	375 articles from Food Labelling News and Food Chemical News	"If you don't act, your rights to access to these products will be taken away "
Academic articles	80 law journal articles	"The FDA has had a long history of bias against dietary supplements"
Interviews w/ diet supplement executives	10 interviews from the New Hope Natural Media and Natural Products Insider	"Supplements aren't food additives, they aren't drugs and they need to be defined"
Interviews with 2 key political actors	2 Retrospective interviews	"They issued statements to reach the public and there were couple of groups on the side of the FDA but they did not have a grassroots movement"
Newspaper articles	115 articles	"It's only Vitamin C. You know, like in oranges"
FDA oral histories	35 transcripts	"It was not pressure from the health food industry that beat us; it was pressure from the American people"
Congressional hearings	6 Transcripts of congressional hearings, 350 pages on Average	"Even our oldest and wisest members know that if they have freedom they will still make mistakes and will suffer for them, but so long as some human must make choices about their health, they prefer to play the role themselves"
Books about the history of supplement regulation	Hawthorne, 2005; Nestle, 2002; Hollenstein, 2007; Apple, 1996 ; Marshall, 1983; Blanchfield, 2000; Fortin, 2009; Feuer, 2013; Offit, 2013, Hurley, 2006; Price, 2015	"Start screaming at Congress and the White House not to let the FDA take our vitamins away"

Table 2: Timeline of events

Year	Event
1906	Food and Drugs Act
1938	Federal Food, Drug and Cosmetics Act
1948	Kordel's case where supplements made by Kordel's firm gets categorized as drugs due to medicinal claims
1973	FDA requires prescriptions for high-dosage forms of vitamins A and D
1974	6-month moratorium on FDA's proposed rules
1976	Proxmire Amendment
1979	FDA proposes OTC Monograph on Vitamins and Minerals Products. FDA proposal dropped due to opposition
1983	E-ferol crisis with 38 infant deaths
1985	FDA entered a collaboration with the Pharmaceutical Advertising Council to combat "medical quackery"
1988	L-tryptophan crisis with 38 deaths and 1500 adverse effects. FDA sharply increases product seizures, tries to regulate the industry as "food additives"
1989	Seven major supplement manufacturers launched the Dietary Supplement Coalition
1990	Using NLEA, FDA proposes a new RDI standard to be printed on the labels, which would result in a reduction in daily allowances for 14 most popular vitamins and minerals
1991	United Natural Products Alliance (UNPA) were launched
1992	Health Freedom Act to define supplements passed the senate but not the house. Dietary Supplement Act, which put a one-year moratorium on the application of the NLEA to supplements
1993	Congress asked three different congressional offices to assess supplements. Two identical bills, one pro and one against dietary supplements introduced in congress
1994	Pro supplement bill becomes the Dietary Supplement Health and Education Act

Table 3a: Extracts of the first-order concepts associated with category work

Dissociation from current category
Redefining Relevant Attributes for Categorizing through component-based arguments (Phase 1): *"Nutrients are not, and never will be, drugs per se, regardless of their level of intake or the intent of their use because they are essential and normal in the body's normal environment. On the other hand, with the exception of so called drugs consisting of hormones, enzymes etc. normally found in the body and occasionally used for substitutive therapy, drugs are substances not normal to the body." (*National Health Federation Bulletin, hearing) *"Vitamin capsules are composed of constituent parts and elements of natural food materials essential for normal nutrition which are found in varying degrees and quantities in various foods and food products"* (Kroger Retail Chain Court Statement, book) *"Vitamins are as much a part of our food as protein, fat, carbohydrates, minerals, water and oxygen. They are needed for the normal functioning of the body. They are not drugs because drugs are not part of our daily food. They are not needed for the normal functions of the body." (*Benjamin Harrow, Professor of Biochemistry, book) **Redefining Relevant Attributes for Categorizing through function-based arguments (Phase 2):***"There are sound reasons for distinguishing the regulation of dietary supplements claims from those of conventional foods. There are many examples of nutrients, herbal products and other supplement ingredients, which appear to offer benefits, only at levels higher than normally found in conventional food. This is the key scientific basis for distinction between these two categories of products."* (Robert Caleb, Herb Research Foundation, Hearing) *"FDA may define "nutritive value" as limited to functions identified in the early part of the century, such as promoting growth, and any amount more than necessary for those functions as a drug requiring drug regulation. But our understanding of nutrient functions and levels for optimal health are expanding rapidly. Those older definitions are no longer sufficient to describe the value that may be obtained from more-than-minimal amounts of natural substances"* (Dr. Gladys Block, 1993 hearing).
Dissociation from category evaluator (Phase 2)
Regulator incompetence arguments: "*We need a more intelligent approach to the regulation of dietary supplements than the FDA's*" (Senator Hatch, 1992, book) *"FDA really doesn't know how to regulate them. Sometimes it classifies them as drugs, sometimes food additives. With certain limited exceptions, I believe neither interpretation is correct."* (Senator Hatch, Hearing*)* *"FDA incompetence may be causing as many as one million deaths a year in this country through the suppression of safe and effective therapies to prevent and treat disease.*" (Life Extension Foundation pamphlet, Specialized news journal) *"The reason the FDA regulations pose potential problems is due to the fact that (the agency's) area of expertise has been synthetic drugs and traditional foods. But these items are not new drugs. They are medicines derived from food sources."* (Spokesperson for the Foundation for Innovation in Medicine, specialized news journal) *"Clearly there is a need for an agency to regulate prescription drugs. However, vitamins fall into an entirely different category and should not be put under the authority of the FDA. "* (Michael Ford of National Nutritional Foods Association, interviews) *"I wonder if it may not be time to consider removing dietary supplements from FDA's purview altogether, so that a regulatory structure appropriate for supplements themselves can be developed, free of the historical baggage and existing constraints "*(Dr. Gladys Block, Hearing). **Regulator bias arguments:** *"The FDA has had a long history of bias against dietary supplements"* (Nutritional Health Alliance, Law journal) *"The most important thing that we would like you to understand today is the deep institutional bias within FDA. This pervasive bias has corrupted recent congressional attempts to expand access to truthful health information through the NLEA act. It has also corrupted honest consumer protection. Nowhere is this bias more evident that the statement by the FDA Dietary Supplement task force, stated on page 2 and page 71, that the FDA mission is to "ensure that the existence of dietary supplement on the market do not act as a disincentive for drug development". In a single statement FDA has laid bare the truth about their preconceived notions about dietary supplements."* (Fred Bingham, Consumer Coalition for Health Choices, Hearing) *"The culture at the FDA has become, "Please the industry. Avoid conflict. They look upon their role as getting out as many drugs as possible."* (Sidney Wolfe, Public Citizens'

Health, interview) *"Pharmaceutical companies are planning new hybrid drug/nutrient supplement combinations, which will likely replace nutrient supplements with price tags comparable to existing drugs. It appears that the agency is intent on crushing the alternative medicine movement, a move that would benefit the pharmaceutical industry by removing one of its principal new sources of competition, but would severely violate health consumers' freedom of choice and would cause needless human suffering and the preventable deaths of tens of thousands of Americans."* (Citizens for health, specialized news journal) *"There is an international conspiracy by the drug industry to eliminate preventive therapy, and the drug industry is a very good friend of the FDA,"* (Gerald Kessler, Nutritional Health Alliance, specialized news journal)
Association with the target category
Food as label: **Phase 1:***"The FDA has very important problems involving the regulation of potent drugs and the high cost of medicines to the American consumer. We submit that it is quite unnecessary for the agency to expend its time and effort in an attempt to restrict the consumer in his freedom to purchase safe food products"(*Milton Bass, legislative counsel of National Nutritional Foods Association, hearing) *"The Proxmire bill would deny FDA the power to prospectively "seize" certain nutritional food products by preventing them from ever being marketed, just because FDA disagrees with a significant block of consumers and nutritionists."* (John Matonis, Health Industries Institute, hearing) **(**Please see the Selective Representation Section below for evidence of labeling in the second phase.)
Selective representation (Phase 2)
Vitamin label for the whole category: *"Hey. Guys. Guys. It's only vitamins. Vitamin C, you know, like in* oranges" (Mel Gibson, newspaper article) *"We cannot guarantee that you will be able to buy vitamins much longer."* (Life extension foundation pamphlet, specialized news journal) *"Write to Congress today or kiss your vitamins goodbye"* (Nutritional Health Alliance advertisement, specialized news journal *"For God's sake, we're talking about vitamin C, B12 injections and Sleepytime tea"*, (Alex Schauss, Citizens for Health, book)

Table 3b: Extracts of the first-order concepts associated with advocacy work

Lobbying legislators
Rational and economic sustainability arguments **Phase 1: (**See Page 20 for supplement makers' efforts to arrange for Senator Proxmire to meet consumers and health stores in his home state Wisconsin.) **Phase 2: "***Mr. Chairman, companies like mine need your help. The industry needs your help. Our very survival is at stake if FDA is allowed to continue these Alice in Wonderland-like theories to arbitrarily keep our products off the marketplace"* (Sidney Tracy, Traco Labs, Specialized news journal) *"Congress can prevent the FDA from dealing a crippling blow to the small businesses of the dietary supplement industry which provides 340,000 jobs"* (Martie Whittekin, President of National Nutritional Foods Association, hearing) *"If the regulations go into effect, the products will be taken off the market because the manufacturers won't take the health-claim labeling off. They are the lifeblood of the industry."* (Attorney Scott Bass, newspaper article) *"One million jobs affected by FDA regulations"* (1992 Preprinted Consumer Letter to Congress, book) *"At an average of $200 million per ingredient spent on testing, the small entrepreneurial companies which make up the dietary supplement industry will dry up"* (Talk-show Host Jerry Jones, book)
Hooking Consumers
Cultural meta-narratives (Freedom of choice) **Phase 1:** *"Even our oldest and wisest members know that if they have freedom they will still make mistakes and will suffer for them, but so long as some human must make choices about their health, they prefer to play the role themselves"* (National Health Federation, hearing) **Phase 2:** *"The NHA believes that the FDA's bias against preventive medicine and the dietary supplement industry will take away the American citizen's health care freedom of choice."* (Nutritional Health Alliance, Specialized news journal) *"We have united our commitment to informed freedom of choice, and have activated to fight the latest round of FDA attacks on this basic human right, to defend our constitutional right to life, to liberty, and the pursuit of happiness. This is not the first time FDA has attempted to restrict access to dietary supplements, and it may not be the last."* (Fred Bingham, Consumer coalition for health choices, Hearing) **"***FDA's interpretation of the NLEA raised constitutional questions about unreasonable restraint of commercial speech under the First Amendment*." (Council for Responsible Nutrition, specialized news journal) *"It is far more permissible in our society to publish pornography, fill the public airways with gratuitous violence and burn the flag than to manufacture health promoting dietary supplements and provide consumers with truthful information about most of their potential benefits."* (Patricia houseman, nutritionist, Hearing*)* *"What is being overlooked by supporters of HR 3642 is the impact this legislation would have on our health care system. Solutions to the health care crisis lie in expanding health care options and protecting a citizen's freedom of choice. The FDA regulations will interfere greatly with consumer access and affordability of dietary supplements, yet some members of Congress are ignoring thousands of calls and letters about this issue from an irate public" (*Tony Martinez, President of National Progressive Health Political Action Committee, newspaper article **Cultural meta-narratives (Heritage)** **Phase 1:** *"You can't laugh these things off. Millions of Americans regard these ideas. Chinese* medicine *is not a joke. It has been practiced for thousands of years"* (Supplement maker, 1973 hearing) *"Our Native Americans took these herbs to heal themselves. Why shouldn't we be allowed to?"*(National health federation president, book) **Phase 2***:"Supplements are "part of our spiritual heritage" because medicinal herbs are mentioned in the Bible. FDA's treading on the essence of democracy and the essence of a spiritual legacy. In the name of 'consumer protection,' the FDA seeks to frighten people, falsely implying that dietary supplements are dangerous. The FDA is against informed choice, the very essence of democracy; it argues that current scientific evidence on nutrition should be withheld from the public until the FDA determines significant scientific agreement. This could take another 20 years…Dietary supplements are an idea whose time has come. The people again demand their rights. Let the people decide. That's how it's done in America."* (National Nutrition Association president, interview)

"This is a freedom of medical choice issue. It is also a preservation of culture issue because the Vietnamese, the Chinese, and the Hispanic people all use herbal medicine." (Roy Upton, Natural Health Care Alliance, book)

Activating consumers

Rhetorical tools (Urgency)

Phase 1: *"There is no health matter of greater urgency. On October 1973, I won't be able to buy vitamin A in high doses without a prescription. This is nutritional tyranny, not consumer protection."* (National Health Federation's legal counsel, hearing)

Phase 2 :*"If we don't get protection now, it may be too late forever"* (Mel Gibson, celebrity activist, newspaper article)

"We received and continue to receive great numbers of letters from the public which express, among other things, concern that vitamins and minerals would no longer be available over the counter and would require the prescription of a physician" (Robert C.Wetherell, Jr. FDA's associate commissioner for legislative affairs, FDA oral history transcripts)

"If you don't act, your rights to access to these products will be taken away." (Nutritional Health Association pamphlet, specialized news journal)

"*Stock up on a one-year supply of nutrient supplements. We cannot guarantee that you will be able to buy vitamins much longer."* (Life extension foundation pamphlet, specialized news journal)

"In November 1992, Congress was persuaded to extend the deadline for regulation for only one year [now until July I, I994|, and that's all the time we are likely to get. Now, we either finish the task of getting the Dietary Supplement Health and Education Act of 1993 passed into law or kiss our vitamins goodbye. (Nutritional Health Association pamphlet, newspaper article)

" If the current FDA proposals were enforced, "50% of all nutritional supplements will no longer be available to Americans within the next 12 to 18 months" (Nutritional Health Association advertisement, book)

Rhetorical tools (Dramatization)

Phase 1:*"If the FDA has its way, Americans concerned about sound nutrition will soon be paying up to three times as much for vitamin and mineral supplements. One anticipates a clandestine organic underground in which pink-cheeked mothers meet shady characters in alleys. The ladies stealthily approach Vita-Pusher as their bright but shifty eyes peer furtively into the shadows for signs of the feds. "How are you fixed for E?" the health conscious mothers ask. "They busted my E contact," grumbles Vita pusher," but I can get you a fix of B-complex or enough wheat germ to last your kids for a week."* (Gary Allen, America Opinion, hearing*)*

"FDA trying to set up a Volstead Act, but with vitamins rather than liquor". (National Health Federation vice president, congressional staff report)

Phase 2: *"We are up against a medical dictatorship that is responsible for the needless suffering and deaths of millions of Americans every year. If the FDA succeeds in blocking our access to these life extension therapies, the death toll will rise considerably. We must take action today to avoid another holocaust" (*Life Extension Foundation, Specialized news journal)

"The FDA actions complained of herein would, if successful, in effect substitute 'diet dictation' as administered from Washington by the FDA Commissioner, acting as 'Diet Czar' for the freedom of choice now, and always, exercised by Americans as to their diets, and arbitrarily bar them from freely employing and consuming such dietary supplements."(National Council of Improved Health, specialized news journal)

"Black jackets, SWAT teams, guns, came through the front door. All of the patients got down on the floor with their hands behind their heads. The offense? Giving B12 vitamin injections." (Loren Israelsen, President of the United Natural Products Alliance, interview)

In 1994, we established the FDA HOLOCAUST MUSEUM (website) where we documented the 70-year reign of terror that the FDA had perpetrated against Americans. We showed the FDA's corrupt practices were causing needless suffering and the deaths of millions of Americans every year. (Life Extension Foundation, website)

"FDA's paternalistic and prohibitionist solution to the supplement problem is a clear and present danger to our lives" (Fred Bingham, Direct AIDS Alternative Information Resources, book)

Coordinating action thru value chain

Use of health stores

Phase 1:*"For example, the diet food store operators, who also tend to sell vitamins, mounted the campaign again which was comparable to the one of 1962, but they misinformed their followers, their clientele, by FDA telling them the FDA was going to prevent vitamins from being sold over the counter."* (Dr. James Goddard FDA commissioner, FDA oral

history transcripts)

"Well, it was started by Clint Miller's (national health federation president) outfit. It was a group sponsored by people that were in this area of quackery, and they promoted letter-writing to people who were interested in these topics, and they flooded the legislature with the proposals to deprive us of jurisdiction. Proxmire got onto it and was adamant about it and put the thing through. There was nothing we could really do to resist it." (William Goodrich, FDA General Counsel, FDA oral history transcripts)

"It was not pressure from the health food industry that beat us; it was pressure from the American people. Now, you can say that's a different way of saying the same thing. But it really isn't. I think we could have beat the health food industry. The most damaging single thing there was that somebody in the health food industry put out, in flyers, that we were trying to take the vitamins and minerals away from the American people and make them prescription drugs (Alexander Schmidt, FDA commissioner, FDA oral history transcripts)

Phase 2: *"The effect of the regulations on the supplement industry is likely to be devastating. Half of the familiar herb and supplement products could disappear from store shelves, putting many distributors and retailers out of business. We can't make money selling beans and potatoes",* (Jerry Sealund, owner of a large health food store in Santa Rosa, California, book)

"So GNC and Tree of Life funded the creation of the Save Our Supplements sign-up center. It was a freestanding information stand that encouraged customers to read the facts and send a letter to their congressman about the issue. Between GNC stores and stores that Tree of Life sold to, there were around 4,000 of those sign-up centers. It was a very big grassroots effort to "save our supplements." (GNC executive John Bresse, interview)

"Company and store owners should explain to employees the importance of grassroots communications to congress. Retailers must immediately begin asking customers to call Washington and tell congress to keep supplements available. Write to Congress today or kiss your supplements good-bye!"(Nutritional Health Association advertisement, newspaper article)

"The stores got together and draped all of their shelves with black cloth to signify that unless the public made their voices heard, the health food industry would cease to exist. The response was incredible, both from consumers and from retailers who willingly took a financial hit to make it happen." (Gerry Kessler, Nutritional Health Alliance association, interview)

"Finally, when Congress was discussing DSHEA in 1994, health food stores gave toll-free numbers for consumers to call Congress. House majority leader Gephart stated that he received over ten thousand phone calls. Another Congressman complained that "constituents were jamming confidential fax machines with letters imploring <Congress> to pass the bill." (Alexander Strauss, Health Foods Business magazine, specialized news journal)

Table 4 Extracts of the first-order concepts associated with FDA actions

Associating with target category
Redefining Relevant Attributes for Categorizing (through function-based arguments) **Phase 1: "***Explicit claims related to prevention or treatment of specific disease conditions render a product a drug*" (FDA statement, law journal) **Redefining Relevant Attributes for Categorizing (through component-based arguments)** **Phase 2: "***Since the gelatin in the supplement capsules is categorized as food, any ingredient added to it would be a food additive, which would require pre-market approval"*(FDA statement, law journal)
Educating
Educational campaign **Phase 1** Medical Quackery Campaign of 1961 *"Consumers lack the information they need to make reasoned choices; consequently are misled into thinking that their diets are inadequate. This ignorance induces consumers to buy products loaded with many times the daily requirement of most, if not all, of the nutrients in the belief that each ingredient makes 'a significant addition to his customary diet."* (Larrick, FDA commissioner, book) *"It is very important to us as a nation that we educate the consumer on the proper use of labels so that they can better identify the foods and choose the foods for a more adequate diet".* (David Kessler, FDA commissioner, book) **Phase 2** Alliance with Pharmaceutical Advertising Council (PAC) for educational campaign *"The PAC and the FDA also issued a joint statement addressed to the presidents of advertising and PR agencies nationwide asking them to cooperate with a joint venture anti-fraud and quackery campaign."* (Mark Blumenthal, Director of the American Botanical Council, book)
Policing
Raids and product seizures **Phase 1:** FDA's 72-page document of product seizures **Phase 2:** See Table 5 for FDA raids
Deterrence
Restrictions of use **Phase 1:** 1968 proposal to require disclaimers on dietary supplements and the 1973 proposal to require prescriptions for high-dosage forms of vitamins A and D. **Phase 2:** FDA blocked market entry to many supplements arguing that food products could not make health claims up to point that FDA rejected 3 of every 4 health claims that diet supplements made. The FDA's reduction in daily allowances to be printed on the 14 most popular vitamins and minerals, as well as its plea to PR agencies worldwide to not publish advertising for supplements also serve as examples of the agency attempting to deter the usage of vitamins among the public.

Table 5: List of raids by FDA

Raid	Reason	Date
The Life Extension Foundation (LEF)	FDA alleged LEF was selling unapproved drugs (vitamins) FDA seized $500,000 worth of vitamins, computers, files, newsletters, personal belongings. Phones were ripped out of the walls and employees terrorized**.**	Feb 26, 1987
Traco Labs	FDA claimed that black currant oil was an unsafe food additive. FDA seized two drums of black currant oil as well as a large quantity of the capsulized product	November, 1988
Highland Labs	FDA claimed that product literature (with false claims) was being shipped with products to customers. FDA said these made COQ10 and GeOXY 132 unapproved drugs.	Fall 1990
Nutricology	FDA raided Nutricology, seized their bank accounts and shut them down for 2 days, charging them with wire fraud, mail fraud, selling unapproved drugs, unsafe food additives, and misbranded drugs. Twelve armed agents conducted an exhaustive search of the company's offices and warehouse.	May 9, 1991
Scientific Botanicals	Alleged labeling violations. FDA seized herbal extract products and literature sent to physicians. FDA forced the company to stop using its patented trade names lest they "mislead the consumer."	Fall 1991
Thorne Research	FDA claimed that vitamin products sold by company were "unapproved drugs." FDA agent and three U.S. Marshalls seized the company's entire stock of $20,000 worth of products and 11,000 pieces of literature intended for physicians.	Dec 12, 1991
Tahoma Clinic (Dr. Jonathan Wright)	After L-tryptophan was banned, Dr. Jonathan Wright continued to prescribe it. The FDA raided him and seized his supply of tryptophan. Dr. Wright filed suit. The FDA retaliated by storming into Wright's clinic with armed sheriffs who terrorized employees and seized vitamins and other natural therapies, allergy screening equipment, computers, bank records, his mailing list, and medical records.	May 6 1992
Ye Seekers	In Feb 1992, Texas health authorities, under the direction of the FDA seized 50 products from several health food stores in Texas including Ye Seekers. Then in June, they seized more than 250 products including aloe vera, zinc, flax seed oil, herb teas, vitamin C and coenzyme Q-10	June 1992
Nature's Way	The FDA seized a quantity of evening primrose oil, both encapsulated and in bulk, from this large manufacturer during a routine inspection. They also seized a truckload of primrose oil on the road. The FDA claimed it was an unapproved food additive.	June 30, 1992
Zerbo's Health Food Store	Reason for the raid was the alleged distribution by 78-year-old Mr. Zerbo of GH-3 to special customers. Armed U.S. Marshalls and FDA agents cleaned off shelves of coenzyme Q-10, selenium, carnitine, and GH-3. Mr. Zerbo and his daughter Claire, who manages the store, were indicted on charges of "illegal drug trafficking"	May 1993
Waco Natural Foods	The FDA was looking for deprenyl citrate, a nontoxic supplement. They entered the store with a search warrant wearing plain clothes. They searched for 4 hours and seemed most interested in possible links to businesses in the Seattle area	May 14, 1993
International Nutrition	Alleged "misbranding" of "illegal drugs" led five FDA agents, a Federal Marshall, and a PR specialist to enter with video cameras (instead of guns) in an effort to prevent a public backlash. FDA seized $1,000,000 worth of vitamin raw materials and products formulated by Dr. Hans Nieper of Germany. Also seized were computers and business records	Jun 24 1993 and Aug. 3, 1993

Source: Life extension magazine.

Table 6 Comparison of dietary supplement versus OTC drug sales growth (1990-1999)

Year	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Supplement Sales ($ billions)	3.2	3.3	3.7	4	5	8.2	9.8	12.6	14.5	16
OTC Sales ($ billions)	10.3	10.9	12.2	13.3	13.5	15.4	16.5	17.4		

Source: Compiled from various industry sources

Table 7. Differences between regulation of drugs, foods, food additives and supplements

Criteria	Drug	Food	Food additives	Supplements
Pre-market approval required	Yes	No	Yes	No
Risk-benefit analysis conducted by FDA before marketing	Yes	No	No	No
Post-marketing reporting or surveillance by industry required	Yes	No	Rarely	No
Burden of proof for demonstrating safety	Manufacturer	FDA	Manufacturer	FDA
Therapeutic claims Allowed	Yes	No	No	No
Structure/function claims allowed	Yes	Yes, focus on effects derived from nutritive value	No	Yes, may focus on **non-nutritive** and nutritive effects

Table 8: List of major associations supporting and against supplements

Against	Supporting
American association of retired persons	National nutritional foods association
American cancer society	Center for responsible nutrition
American college of physicians	Nutritional health alliance
American college of preventive medicine	Citizens for health
American health association	American preventive medical association
National association of attorneys general	Foundation for innovation in medicine
Association of schools of public health	National nutritional foods assoc., Northern California Region
Association of state and territorial health officials	Utah natural products alliance
Center for science in the public interest	San Francisco alternative treatment committee
Society for nutrition education	Herb Research Foundation
The American Dietetic Association	Public Citizens' Health
National food processors association	Life Extension Foundation
Pharmaceutical Advertising Council	National health federation
Consumers Union	Consumer coalition for health choices
The public citizen	National progressive health political action committee
American Society of Clinical Nutrition	National council of improved health
American Medical Association	Health Industries Institute

Table 9: List of questionable claims made by supplement makers and contested by FDA

Ingredient	Claim
Garlic	Inhibits growth of bacterial and viral infections
Raw Thymus	Prevents AIDS, cancer and herpes
Yucca	Helps fight arthritis and gout
Hawthorne	Relieves high blood pressure and hypertension
Horsetail	Speeds the healing of fractured bones
Shark Cartilage	Eradicates cancerous tumors
Parsley	Removes small kidney and gallstones
Comfrey plant	Fights infection and kidney/bladder ailments

Source: Food and Drug Administration, July, 1993.

Biographical Sketches

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